Supreme Court, U.S.
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No.

IN THE
Supreme Court of the United States

NUCLEONICS, INC.,

Petitioner,

v.

BENITEC AUSTRALIA, LTD.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1) Did the Federal Circuit err in determining that there was no Article III jurisdiction over a declaratory judgment *counterclaim* for patent invalidity where

(i) the patentee had brought suit for infringement,

(ii) then dismissed its case without prejudice and without a full covenant not to sue in the future,

thereby forcing the defendant to abstain from allegedly-infringing activities and inflicting current and ongoing financial and competitive hardships and risks as a result of the unresolved allegation, while the patent has escaped scrutiny?

2) Did the Federal Circuit err by improperly shifting the jurisdictional burden to the defendant instead of requiring the plaintiff-patentee to show that the jurisdiction that "necessarily" exists over invalidity counterclaims had been "entirely terminated"?

PARTIES TO THE PROCEEDING

Pursuant to Rule 14.1(b), we note that the caption here identifies all of the parties that appeared below in the U.S. Court of Appeals for the Federal Circuit – specifically, petitioner Nucleonics, Inc. and respondent Benitec Australia, Ltd.

RULE 29.6 STATEMENT

Nucleonics, Inc. is a privately-held corporation. There are no parent corporations of Nucleonics, Inc. nor are there any publicly-held companies that own 10 percent or more of the stock of Nucleonics, Inc.

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OPINIONS BELOW

The opinion of the U.S. Court of Appeals for the Federal Circuit is reported at 495 F.3d 1340 and is supplied in the Appendix ("App.") at 1a-35a. The opinion of the U.S. District Court for the District of Delaware is unreported in F.Supp.2d, but is accessible at 2005 WL 2415959 and is supplied at App. 36a-45a.

JURISDICTION

The decision of the Federal Circuit was entered on July 20, 2007. The Federal Circuit denied a petition for rehearing or rehearing *en banc* on October 4, 2007 (App. 49a-50a). This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

"The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority. . . ."

U.S. CONST. ART. III, SEC. 2.

* * * * *

"In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief

is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such."

28 U.S.C. § 2201.

STATEMENT OF THE CASE

This case presents a fundamental constitutional issue regarding Article III "case or controversy" jurisdiction over patent invalidity and unenforceability[1] declaratory judgment *counterclaims* where a lawsuit for patent infringement has already been instituted against the defendant.

The facts of this case – set out below – reveal a plaintiff-patentee that has been permitted to manipulate the system so as to use the federal patent grant to inflict competitive and economic injury and maintain the very real threat of a future lawsuit (regarding the exact same technology and patent at issue in this suit), while keeping the patent immune from scrutiny in the only courts that have exclusive jurisdiction over patent matters.

As discussed in greater detail in "Reasons for Granting the Petition" below, the denial of jurisdiction over the petitioner's declaratory judgment counterclaims here conflicts with this Court's holdings in *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993); *Altvater v. Freeman*, 319 U.S. 359 (1943); and the recent *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007) case; as well as with a long line of Circuit Court cases.

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[1] Referred to collectively as "invalidity counterclaims" throughout this Petition.

Of equal significance, the denial of jurisdiction here frustrates the Declaratory Judgment Act and hinders innovation generally and in the biotechnology field. It allows invalid patents to be wielded by trolls (both in and out of court) to inflict significant harm with no consequences for the patentee, no concomitant societal benefit and no constitutional justification.

A. The Parties and The Technology

Nucleonics, Inc. is a small, privately-held biotechnology startup company that is pursuing "gene-silencing" technology. Nucleonics uses a technique known as DNA-based RNA interference (RNAi) as its only method of gene-silencing for all applications.

This technology can be used to treat diseases – including use as a treatment for viral infections in animals and humans. It can also be used to study the role that particular genes play in cells by comparing cells that have had a gene silenced with others that have a functioning version of the gene.

Nucleonics has been pursuing various applications of their technology including: a treatment for human hepatitis B; potential prostate and ovarian cancer treatments; possible animal applications; and an aborted collaboration with one of the world's largest pharmaceutical companies to engage in basic research.

As a non-public company, Nucleonics depends upon funding from venture capitalists and corporate partners who choose to invest in and/or partner with Nucleonics.

Benitec Australia Ltd. is a public Australian corporation. Benitec was the plaintiff in the District Court in this case. Among its patent holdings is U.S. Patent 6,573,099 (the '099 patent) entitled "Genetic Constructs for Delaying or Repressing the Expression of A Target Gene" (claiming both genetic constructs and methods of gene-silencing).

Benitec has interpreted its patent very broadly to cover countless, if not all, techniques of gene silencing of *any gene* in *any animal* of *any species* by *any mechanism* for research or commercialization. Indeed, Benitec has publicly asserted that it holds dominant patent rights over all DNA-based RNAi – the sole and entire focus of Nucleonics' research efforts – stating in one Annual Report:

> Benitec's patent estate represents a dominant position in DNA-directed gene silencing, and potentially the dominant position in RNAi application for humans and mammals.

(App. at 51a).

B. Proceedings Below

1. The District Court Proceedings

On March 22, 2004, plaintiff Benitec Australia Ltd. sued three separate defendants – including petitioner Nucleonics, Inc. – for infringement of the '099 patent in the United States District Court for the District of Delaware. The District Court had jurisdiction

pursuant to 28 U.S.C. §§ 1331, 1338 and 2201 and Article III of the U.S. Constitution.

Benitec's suit against Nucleonics was brought on the eve of Nucleonics' attempts to raise operating capital. Benitec knew of Nucleonics' fundraising and timed its lawsuit for maximum disruptive effect, boldly stating in a news release:

> Benitec commenced proceedings against Nucleonics, Inc. in March of 2004 as they ***were obviously infringing on Benitec's issued patent estate,*** of which Nucleonics was aware. ***Benitec was advised that Nucleonics was in the process of raising in excess of U.S. $40 million*** from U.S. investors using Benitec's ddRNAi technology, which was the subject of an issued patent in the United States dated June 2003. ***Benitec thought it necessary and important to bring to the attention of the prospective investors in Nucleonics the existence of Benitec's issued patents*** and to ensure that Benitec could not be criticized at a later date of having known of infringement, but of having taken no action to protect Benitec's intellectual property, or the interests of Nucleonics' own investors.

(App. at 52a) (emphasis added).

During the course of the litigation, Benitec broadly accused *all* Nucleonics' activities of infringement, including non-commercial basic research and development efforts involving both human and

animal gene silencing. Benitec specifically stated to the District Court:

[REDACTED]

(App. at 54a) (emphasis added).

Discovery revealed several grounds of invalidity, including prior art and also a very significant inventorship dispute that was never revealed to the U.S. Patent Office. The named inventor started his own company, Benitec, and never gave credit or assignment to his former colleagues who conceived the invention. Counterclaims for invalidity and unenforceability were pursued by Nucleonics. Hague Convention testimony in Australia, confirming the inventorship fraud, was

obtained in June 2005.[2]

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[2]

[REDACTED]

(cont'd)

Shortly after the Australian Hague Convention testimony was obtained, Benitec moved to "voluntarily" dismiss the entire litigation without prejudice. Benitec's stated rationale for seeking dismissal was its new-found view that Nucleonics' activities were supposedly presently immune from infringement in light of this Court's intervening decision in *Merck v. Integra Lifesciences*, 545 U.S. 193 (2005) (regarding the scope of the "infringement safe harbor" of 35 U.S.C. §271(e)(1)).

However, as both the majority and dissent in the Federal Circuit recognized, Benitec's maneuver may have had more to do with concerns about an invalidity finding. *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495

(cont'd)

[REDACTED]

F.3d 1340, 1342-43, 1351(Fed. Cir. 2007) (App. at 4a, 25a and 27a).[3]

Benitec's motion never conceded that Nucleonics' activities do not infringe the Benitec patent as a technological matter, nor did Benitec covenant not to sue again on the same patent in the future. Benitec argued only that the temporary safe harbor of *Merck v. Integra* applied.

Defendant Nucleonics opposed the motion, arguing that there was jurisdiction over its counterclaims. Nucleonics also filed a Declaration (App. at 57a-63a) from its CEO outlining the harm that it had experienced, and would continue to experience, as a result of the lawsuit and the continuing controversy and threat. These harms included the loss of at least one investor, continuing questions from other prospective investors about this issue and a forced withdrawal by Nucleonics from a research partnership with a major pharmaceutical company in light of concerns about the litigation. (App. at 60a-61a at ¶14).

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[3] *Id.* at 1342, App. at 4a ("In 2005, Benitec encountered a pair of obstacles. First, Nucleonics received evidence indicating that the inventor named in the '099 patent may have misappropriated the idea for the invention from others. . . .Nucleonics obtained testimony in June 2005 from Australian scientists . . . that they contributed to the subject matter of the '099 patent. Neither, however, is named as an inventor of the '099 patent."); and *Id.* at 1351, App. at 25a and 27a (Dyk, J., dissenting) ("Here the patentee's manipulative efforts to defeat jurisdiction are clear enough.... As the majority appears to recognize, op. at 1342-43, the motion may well have been motivated by a desire to avoid a patent invalidity determination.").

On September 29, 2005, without oral argument, the District Court applied the then-prevailing "apprehension of an imminent lawsuit" test and concluded as a matter of law that there was no jurisdiction over Nucleonics' declaratory judgment counterclaims. The entire case was dismissed.

Placing the burden on counterclaimant Nucleonics to "establish[ ] the existence of a case or controversy" (App. at 40a and 42a), the District Court found that Nucleonics *did* reasonably apprehend being sued, given Benitec's demonstrated litigiousness and public pronouncements. Nonetheless, the court stated:

> [although] Nucleonics has demonstrated a reasonable apprehension of suit, . . . [it] has not demonstrated that it has produced or has prepared to produce a product that would be the target of an infringement lawsuit by Benitec.

Benitec Austl. Ltd. v. Nucleonics, Inc., No. 04-0174, slip op. at 6-8, 2005 WL 2415959 (D. Del. Sept. 29, 2005) (App. at 41a-42a).

The District Court did not discuss or analyze the uncontested fact – from the Declaration of Nucleonics' CEO – that Nucleonics had been coerced by the litigation to abstain from allegedly-infringing activity that independently would have supported jurisdiction. This was, of course, in September 2005 – well before this Court's January 2007 discussion of the effect of this type of coercion on jurisdiction in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007).

2. The Federal Circuit Appeal

The District Court's decision was timely appealed to the Federal Circuit.[4] The Court of Appeals had jurisdiction over the appeal pursuant to 28 U.S.C. § 1295(a)(1) and Article III of the U.S. Constitution.

Nucleonics argued, *inter alia*, that under this Court's precedent in *Cardinal Chemical Co. v. Morton Int'l Inc.*, 508 U.S. 83 (1993), and *Altvater v. Freeman*, 319 U.S. 359 (1943), the initiation of a patent infringement suit "necessarily" provides the district court with jurisdiction over counterclaims for declaratory judgment of invalidity and/or unenforceability. It was further urged that such jurisdiction is not divested unless the patentee provides a full covenant not to sue with respect to past, present and *future* activities – in the language of *Cardinal Chemical* unless the controversy is "entirely terminated." 508 U.S. at 98.

During oral argument on December 6, 2006, counsel for Benitec admitted that:

> "We have not made that statement that we would forebear suing them."

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[4] Nucleonics timely filed a "Notice of Appeal" with the District Court on October 27, 2005. The appeal was docketed by the Federal Circuit on December 14, 2005. Appellant Nucleonics filed its Opening Brief with the Federal Circuit on February 13, 2006. Benitec filed its Opposition on April 27, 2006 and a Reply was filed on June 6, 2006. Oral argument was had on December 6, 2006.

Benitec Australia, Ltd. v. Nucleonics, Inc., 495 F.3d at 1354, App. at 33a (quoted by Dyk, J., dissenting).

On January 9, 2007, this Court decided *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007) (discussing *Cardinal Chemical* and *Altvater* – the same authority relied upon by Nucleonics in support of its appeal).

In response, the three-judge Federal Circuit panel issued an Order on January 10, 2007 inviting supplemental briefing as to the effect of *MedImmune* on the present case. (App. at 46a-48a).

Nucleonics' supplemental briefing pointed out that, as in *MedImmune*, it had been forced, by the patentee's litigation and threats, to abstain from allegedly infringing activity – in the form of a collaborative project with one of the world's largest pharmaceutical companies involving non-safe-harbor activities. That abstained-from activity would have independently supported jurisdiction had it continued. Under *MedImmune*, such forced abstention does not vitiate jurisdiction. *MedImmune*, 127 S. Ct. at 772-73 and 775.

3. The Federal Circuit Split Decision

On July 20, 2007, in a 2-to-1 decision,[5] the Federal Circuit affirmed the finding of no jurisdiction over Nucleonics' counterclaims.

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[5] The majority opinion was authored by District Judge Whyte sitting by designation and was joined by Circuit Judge Rader. Circuit Judge Dyk dissented.

The majority accepted that this Court's decision in *Cardinal Chemical* is both pertinent to, and dictates that district court jurisdiction "necessarily" exists over invalidity counterclaims where a defendant has been sued for patent infringement. *Benitec v. Nucleonics*, 495 F.3d at 1344, App. at 9a.

However, the majority gave no further credence to *Cardinal Chemical* on the question of what is required to divest existing jurisdiction or who has the burden thereafter to show the continuing existence or non-existence of jurisdiction over the counterclaims at the district court level.

Repeating the District Court's analysis, the majority placed the burden on defendant Nucleonics to justify continuing jurisdiction over its counterclaims[6] – discounting the statement in *Cardinal Chemical*, 508 U.S. at 98, that:

> While the initial burden of establishing the trial court's jurisdiction rests on the party invoking that jurisdiction, once that burden has been met courts are entitled to presume, absent further information, that the jurisdiction continues

as not pertinent to district courts. *Benitec v. Nucleonics*, 495 F.3d at 1345, App. at 10a.

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[6] *Benitec v. Nucleonics*, 495 F.3d at 1344, App. at 9a ("The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since.").

With the burden placed on Nucleonics, the Federal Circuit began its substantive analysis by noting that the "reasonable apprehension of imminent suit" test had been disapproved and abandoned in light of this Court's *MedImmune* holding. *Benitec v. Nucleonics*, 495 F.3d at 1343-44, App. at 7a-8a. Nonetheless, the majority stated that:

> A useful question to ask in determining whether an actual controversy exists is what, if any, ***cause of action*** the declaratory judgment defendant [the patentee] may have against the declaratory judgment plaintiff [e.g., defendant Nucleonics].

Benitec v. Nucleonics, 495 F.3d at 1344, App. at 8a-9a (emphasis added) (citing to the pre-*MedImmune* case of *MicroChip Tech. Inc. v. Chamberlain Group, Inc.*, 441 F.3d 936, 943 (Fed. Cir. 2006)).

Applying this as its guidepost, the majority concluded that:

> Nucleonics has therefore not met its burden of showing that it is engaged in any ***present activity*** that could subject it to a ***claim of infringement*** by Benitec. *See MicroChip Tech.*, 441 F.3d at 943.

Benitec v. Nucleonics, 495 F.3d at 1348, App. at 19a (emphasis added). This "present activity" / "claim of infringement" approach – suspiciously reminiscent of the disapproved "imminent suit" test – was then equated with a lack of *MedImmune* "immediacy and reality." *Id.*

This conclusion was reached notwithstanding evidence of present day coerced abstention, present day expenditure of tens of millions of dollars on research within the very technology allegedly covered by Benitec's patent, infliction of business harm, public statements to investors and an actual lawsuit for infringement.

With respect to Nucleonics' future activities (based on the exact same technology that Benitec claims its patent broadly covers and had already sued on and refused to covenant not to sue on again), the majority concluded:

> We do not express an opinion on whether Nucleonics's animal work could ever be the subject of an infringement suit. We merely hold that Nucleonics did not carry its burden of showing an existing justiciable controversy.

Benitec v. Nucleonics, 495 F.3d at 1349, App. at 21a.

There is no discussion in the majority opinion of the allegedly-infringing work that Nucleonics had been forced to abstain from – highlighted in Nucleonics' supplemental briefs as a ground for jurisdiction under *MedImmune* (assuming that Nucleonics had the jurisdictional burden).

4. The Dissent

Judge Dyk, in dissent, urged that:

> Supreme Court precedent requires that, if a patentee files an infringement lawsuit and the particular claim of infringement is mooted, a counterclaim for invalidity should not be dismissed unless the patentee demonstrates that there is no possibility of a future controversy with respect to invalidity. *See Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 98, 113 S. Ct. 1967, 124 L.Ed.2d 1 (1993). In my view, Benitec made no such showing.

Benitec, 495 F.3d at 1350, App. at 23a. Further describing Benitec's failure, the dissent noted:

> Benitec offered no covenant with respect to future human or animal products or animal research.

Id. at 1352, App. at 28a; and:

> [W]hen asked at oral argument whether Benitec was "promising not to sue [Nucleonics] for animal product research that they begin" the day after argument, Benitec's counsel responded, "We have not made that statement that we would forebear suing them."

Id. at 1354, App. at 33a.

Explaining the reason for requiring Benitec – who brought the lawsuit – to bear the burden of demonstrating that the controversy is fully terminated, the dissent, quoting from *Cardinal Chemical*, stated:

> "[i]f . . . a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction of a complaint or counterclaim under the Act." *Id.* at 96, 113 S. Ct. 1967 (emphasis in original). The Court explained that while the initial burden of establishing declaratory judgment jurisdiction rests on the party seeking a declaratory judgment, "once that burden has been met courts are entitled to presume, absent further information, that jurisdiction continues." *Id.* at 98, 113 S. Ct. 1967.
>
> In explaining the policy reasons for shifting the burden, the Court stated that "[a] company once charged with infringement must remain concerned if it develops and markets similar products in the future." *Id.* at 99-100, 113 S. Ct. 1967. Moreover, declining jurisdiction over invalidity counterclaims "creates [the] potential for relitigation and imposes ongoing burdens on competitors who are convinced that a patent [is] invalid." *Id.* at 101, 113 S. Ct. 1967.

Benitec, 495 F.3d at 1352, App. at 29a-30a.

* * * * *

We seek a writ of certiorari here to address this jurisdictional issue and ultimately to reinstate petitioner Nucleonics' counterclaims for invalidity and unenforceability.

REASONS FOR GRANTING THE PETITION

I. This Case Presents An Important Constitutional Issue Regarding Article III Jurisdiction – The Federal Circuit's Opinion Departs From this Court's Jurisprudence, Frustrates the Declaratory Judgment Act and Stifles Innovation

This case presents an important issue of fundamental constitutional jurisprudence regarding Article III jurisdiction that is of significance to patent (and other) controversies. The specific question is:

> whether a patentee that has sued for infringement can divest the federal court's jurisdiction over the defendant's invalidity counterclaims by withdrawing its suit without prejudice and without a full covenant not to sue again?

Such a result leaves the defendant in a state of limbo – experiencing a continuing threat (with all the business harm and chill on activity that entails), but incapable of challenging the validity of the patent in the only courts that have exclusive jurisdiction over patent matters.

The resolution of this issue is important to defendants in every patent infringement suit (and there

are several thousand such suits filed each year that relate to billions of dollars of commerce and research), to the investors and potential investors in those companies and to the public policy of advancing innovation. While valid patents serve to promote innovation, invalid patents (particularly those that are immune from scrutiny but are being used extra-judicially as business weapons) chill innovation and investment in innovation.[7] That chill is particularly harsh for startup biotechnology companies (often the incubators for novel and groundbreaking medical advances) that are dependent on financing from investors who are highly sensitive to patent threats.

The Federal Circuit's decision here also raises broader concerns (beyond patent matters) with respect to Article III jurisprudence generally and also counterclaim jurisdiction. The decision – already cited by numerous other courts[8] – conflicts with fundamental and long-held understandings and precedent from this Court and various Circuit Courts regarding the all but self-evident proposition that a controversy (and related

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[7] This Court has long recognized that public policy favors challenges to invalid patents. *See, e.g., Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100 (1993); *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971); *Lear, Inc. v. Adkins*, 395 U.S. 653, 663-64 (1969); and *Altvater v. Freeman*, 319 U.S. 359, 364-65 (1943).

[8] A recent Shepard's of the Federal Circuit's barely five-month old ruling (495 F.3d 1340) indicates that it has already been cited *eleven* times by district courts in the Second, Third, Sixth, Seventh, Eighth and Ninth Circuits, often dismissing counterclaims, and is discussed in one Law Review article.

counterclaim jurisdiction) exists where a lawsuit (patent or other) has already been initiated and that jurisdiction is not extinguished where the lawsuit is withdrawn while the right to sue again is reserved.

Thus, this Court has specifically held that Article III jurisdiction over invalidity counterclaims "necessarily" exists where a patentee has already sued, stating in *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95-96 (1993):

> Merely the desire to avoid the threat of a "scarecrow" patent, in Learned Hand's phrase, may therefore be sufficient to establish jurisdiction under the Declaratory Judgment Act. ***If,*** in addition to that desire, ***a party has actually been charged with infringement of the patent, there is necessarily, a case or controversy adequate to support jurisdiction of a complaint, or a counterclaim under the Act.***

(emphasis added). In addition, this Court has recognized that counterclaim jurisdiction is not disposed of even in instances where the infringement issue is completely resolved. *Id.* at 97-98; *Altvater v. Freeman*, 319 U.S. 359, 363 (1943). *See also Leach v. Ross Heater & Mfg. Co.*, 104 F.2d 88, 91 (2d Cir. 1939) (permitting counterclaims and noting the rationale was to avoid having "the patentee . . . withdraw his suit without prejudice and continue broadcasting assertions of infringement"); *Dale Elec., Inc. v. R.C. Elec. Inc.*, 488 F.2d 382, 390 (1st Cir. 1973) (reversing dismissal of counterclaim for invalidity despite dismissal of complaint

for infringement); *Trico Prods. Corp. v. Anderson Co.*, 147 F.2d 721, 722-23 (7th Cir. 1945); *Lackner Co. v. Quehl Sign Co.*, 145 F.2d 932, 934 (6th Cir. 1944) (finding jurisdiction over declaratory judgment counterclaims despite (as here) an offer to dismiss and forgive past infringement, stating "In [*Altvater v. Freeman*] there was a decision of noninfringement, but nevertheless the Supreme Court held that the counterclaim attacking validity was not disposed of by dismissal of the bill. Here, as pointed out, there has been no decision of noninfringement, and infringement is still asserted."); *Dominion Elec. Mfg. Co. v. Edwin L. Wiegand Co.*, 126 F.2d 172, 174-75 (6th Cir. 1942) (commenting on *Leach* in a trademark dispute: "the principal ground for sustaining the counterclaim was that the patentee might withdraw his suit and continue broadcasting assertions of infringement"). *Cf. Sterling Aluminum Prods., Inc. v. Bohn Aluminum & Brass Corp.*, 298 F.2d 538, 539 (6th Cir. 1962) (complaint charged infringement of all patent claims, later patentee sought to limit accusation to only two claims, however, jurisdiction found over invalidity counterclaims as to *all* patent claims).

The Federal Circuit's opinion here also conflicts, in at least two respects, with this Court's approach to federal court jurisdiction in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007). First, the Federal Circuit opinion attempts a de facto return to the "imminent suit" test for Article III declaratory judgment jurisdiction that was disapproved in *MedImmune*. Second, the Federal Circuit opinion was

utterly silent with regard to the evidence of Nucleonics' coerced abstention from allegedly infringing activity – a basis for maintaining jurisdiction under *MedImmune* (assuming that the burden was on Nucleonics to show jurisdiction even after they were sued).

By failing to recognize jurisdiction here over declaratory judgment counterclaims – in contravention of this Court's precedent and that of numerous other Circuit Courts – the Federal Circuit's decision frustrates, without any constitutional justification, the purpose of the Declaratory Judgment Act. That Act was designed to address the very type of scenario at play here, where:

> a patent owner engages in a *danse macabre*, brandishing a Damoclean threat with a sheathed sword. . . . Before the Act, competitors victimized by that tactic were rendered helpless and immobile so long as the patent owner refused to grasp the nettle and sue. After the Act, those competitors were no longer restricted to an *in terrorem* choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by suing for a judgment that would settle the conflict of interests.

Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 734-35 (Fed. Cir. 1988) (quoted with approval by this Court in *Cardinal Chemical*, 508 U.S. at 95-96).

The Federal Circuit's departure from long-prevailing law is not simply constitutionally infirm, but works a deep mischief on the dynamic between

patentees and alleged infringers. The patentee trolling for a quick royalty or a damaging economic blow to a competitor can bring suit, pressure the accused, and then in the face of adverse evidence withdraw – while retaining the right to sue again and thereby continuing the very real world onslaught (otherwise known as a controversy) against its adversary.

II. The Federal Circuit's Decision Conflicts With This Court's Holdings In *Cardinal Chemical* and *Altvater*, As Well As With Various Other Circuit Court Holdings – Eviscerating Declaratory Counterclaims and Giving Alleged Infringers No Recourse

The determination of whether a "controversy" exists between a patentee and a putative infringer, where *no* infringement lawsuit has been brought, focused, prior to *MedImmune*, on the probability or likelihood of an actual lawsuit – applying the two-prong "reasonable apprehension of an imminent lawsuit" test.

However, setting *MedImmune* aside for the moment, when an actual lawsuit *has* been filed by the patentee, there is no need to ponder the "probability" or the "likelihood" or the "reasonableness" of apprehending suit.

The lawsuit – and the controversy – are self-evident. They exist.

Thus, this Court in *Cardinal Chemical*, 508 U.S. at 95-96, stated simply that there "necessarily" exists a case or controversy over invalidity counterclaims where

the defendant has already been sued for patent infringement. *See also Id.* at 96 ("perfectly clear that the District Court had jurisdiction" over counterclaims).

And this Court went further. It said that the "necessarily" existing jurisdiction over invalidity counterclaims should be *presumed* to *continue* by the "courts" – not distinguishing district or appellate "courts" as the site for the presumption. *Cardinal Chem.*, 508 U.S. at 98. The burden is shifted to the patentee-plaintiff to show that the controversy is "entirely terminated" (*Id.* – albeit, in this passage, referring to events in the appellate court) or "completely" ended (*See Leach v. Ross Heater & Mfg. Co.*, 104 F.2d 88, 91-92 (2d Cir. 1939) (referring to the district court)).

As this Court further explained in *Altvater v. Freeman*, 319 U.S. 359 (1943), even a judgment of non-infringement – which would provide absolute certainty (unlike this case) that a particular technology does not and never will infringe – does not vitiate the invalidity counterclaim:

> We have here not only bill and answer but a counterclaim. Though the decision of non-infringement disposes of the bill and answer, it does not dispose of the counterclaim which raises the question of validity.

Altvater, 319 U.S. at 363.

Indeed, one of the key reasons for counterclaims is to *hold* the patentee in court until the matter is *fully*

resolved. This purpose was understood very early on. In a case virtually identical to this one, the Second Circuit held that counterclaims are to be permitted where a patentee sued and then attempted to dismiss both its lawsuit and the defendant's counterclaims, ostensibly because it discovered that the defendant did not infringe. *Leach v. Ross Heater*, 104 F.2d at 90-91. Inherently recognizing the continuing controversy, the court stated:

> The patentee may, for all that the defendant knows, ***withdraw his suit without prejudice and continue broadcasting assertions of infringement***. . . . While it may turn out at trial that a decision on the merits of the plaintiff's bill will ***dispose of the controversy*** between the parties ***completely***, in which case the counterclaim may be dismissed, we are of the opinion that it was error to strike out the counterclaim at so early a stage.

Leach, 104 F.2d at 91-92 (emphasis added) (cited by this Court in *Altvater v. Freeman*, 319 U.S. at 363 n.3).

The rule of law that emerges is that once a patentee sues they have created invalidity counterclaim jurisdiction which can only be removed by a complete disposal of the controversy – e.g., a full covenant not to sue. The burden is shifted and the patentee must act to divest jurisdiction.

However, the Federal Circuit has resisted this rule, insisting that a patentee can withdraw without a full covenant not to sue again and the accused alleged

infringer must show, essentially, that another lawsuit is imminent in order to maintain the counterclaims. Both in this case, and in *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed. Cir. 1995), the Federal Circuit has sought to distinguish *Cardinal Chemical* as not applicable to district court jurisdiction.

However, as Judge Dyk said in dissent here, there is no logical reason to so limit *Cardinal Chemical. See Benitec v. Nucleonics*, 495 F.3d at 1353, App. at 30a ("Contrary to the majority, *Cardinal Chemical* cannot be limited to mootness at the court of appeals level."). Furthermore, in *MedImmune* – a case clearly having to do with district court jurisdiction – this Court specifically discussed *Cardinal Chemical* as guiding precedent. *MedImmune*, 127 S. Ct. at 774 n.11. And, of course, *Altvater* relates directly to district court jurisdiction, as does the Second Circuit's *Leach v. Ross Heater* case (cited by *Altvater*) and its progeny. *See Dale Elec., Inc. v. R.C. Elec. Inc.*, 488 F.2d 382, 390 (1st Cir. 1973); *Trico Prods. Corp. v. Anderson Co.*, 147 F.2d 721, 722-23 (7th Cir. 1945); *Lackner Co. v. Quehl Sign Co.*, 145 F.2d 932, 934 (6th Cir. 1944); *Dominion Elec. Mfg. Co. v. Edwin L. Wiegand Co.*, 126 F.2d 172, 174-75 (6th Cir. 1942). *Cf. Sterling Aluminum Prods., Inc. v. Bohn Aluminum & Brass Corp.*, 298 F.2d 538, 539 (6th Cir. 1962).

Ironically, in an earlier incarnation, even the Federal Circuit apparently recognized this principle of law, stating with approval (albeit in dicta):

> The cases in which the courts have retained jurisdiction on the basis of counterclaims despite

> the plaintiff's voluntary dismissal of the complaint are legion.

Aerojet-General Corp. v. Machine Tool Works Ltd., 895 F.2d 736, 743 (Fed. Cir. 1990). *Cf. also Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340 (Fed. Cir. 2005) (legal conclusion of non-infringement does not defeat jurisdiction over invalidity counterclaims).

The consequence of the current Federal Circuit's improper shifting of the burden is that counterclaims are essentially meaningless. The very purpose that they were designed to achieve – preventing the patentee from walking away without fully resolving the matter, as described in *Leach v. Ross Heater* – has been vitiated.

As a result, alleged infringers are now left to be gored – and gored again. Article III does not mandate that approach. Indeed, a proper reading of this Court's precedent requires the opposite. Countless patent, trademark and other cases with counterclaims are affected by the Federal Circuit's error – and for this reason, the Petition should be granted.

III. The Federal Circuit's Decision Conflicts With *MedImmune* and Forces Alleged Infringers to "Bet the Farm"

Assuming, *arguendo*, that the Federal Circuit was correct in assigning the burden to defendant Nucleonics to show jurisdiction, their decision here nonetheless reaches the wrong result by ignoring the holding of *MedImmune* in two key respects. Each of these errors sets up a false precedent that will undo the effect of *MedImmune* in the lower courts.

A. A Return to the "Imminent Lawsuit" Test

First, the test employed by the Federal Circuit here is, except in name, a clear return to the disapproved "reasonable apprehension of imminent lawsuit" test. Please see *Benitec v. Nucleonics*, 495 F.3d at 1344, App. at 8a-9a – essentially defining the test for jurisdiction as whether Nucleonics' activities are amenable to an imminent "cause of action" and quoting from the pre-*MedImmune* case of *MicroChip Tech. Inc. v. Chamberlain Group, Inc.*, 441 F.3d 936, 943 (Fed. Cir. 2006), as follows:

> Without an underlying legal cause of action, any adverse economic interest that the declaratory plaintiff may have against the declaratory defendant is not a legally cognizable interest sufficient to confer declaratory judgment jurisdiction.

However, to the contrary, *MedImmune* recognized (1) that an imminent lawsuit is not needed for declaratory judgment jurisdiction – indeed jurisdiction can exist in the absence of any possibility of a lawsuit[9] and (2) that the infliction of economic harm

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[9] *MedImmune*, 127 S. Ct. at 774 n.11 ("Even if *Altvater* could be distinguished as an 'injunction' case, it would still contradict the Federal Circuit's 'reasonable apprehension of suit' test (or, in its evolved form, the 'reasonable apprehension of *imminent* suit' test, *Teva Pharm, USA Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (2005)). A licensee who pays royalties under compulsion of an injunction

(cont'd)

through coercion with a patent supports jurisdiction, observing:

> "to imperil a man's livelihood, his business enterprises, or his solvency [was] ordinarily quite as coercive" as for example "detaining his property."

MedImmune, 127 S. Ct. at 774 (quoting from F. Woodward, The Law of Quasi Contracts § 218 (1913), which was cited in *Altvater*). *MedImmune* explained that such coercion leaves the party threatened by the patent with a Hobson's choice of engaging in acts of alleged infringement or abstaining from those acts and

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(cont'd)

has no more apprehension of imminent harm than a licensee who pays royalties for fear of treble damages and an injunction fatal to his business. The reasonable-apprehension-of-suit test also conflicts with our decisions in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273, 61 S. Ct. 510, 85 L. Ed. 826 (1941), ***where jurisdiction obtained even though the collision-victim defendant could not have sued*** the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured; and *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239, 57 S. Ct. 461, 81 L. Ed. 617 (1937), where jurisdiction obtained even though the very reason the insurer sought declaratory relief was that the insured ***had given no indication that he would file suit***. It is also in tension with *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 98, 113 S. Ct. 1967, 124 L. Ed.2d 1 (1993), which held that appellate affirmance of a judgment of non-infringement, ***eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity.***" (emphasis added)).

suffering economic detriment thereby. Under either scenario, there is jurisdiction, because:

> The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III.

Id., 127 S. Ct. at 775.

Here, by effectively reinstating the "imminent lawsuit" standard, the Federal Circuit ignores economic harm and coercion and forces a fledgling biotech company to "bet the farm" – by either continuing to invest in a technology already accused of infringement or closing shop.

B. Failure to Consider "Coerced Abstention"

This leads to the Federal Circuit's second departure from *MedImmune*. There was no consideration of the fact that Nucleonics was coerced to end a collaboration, involving allegedly infringing activity, with a major multi-national pharmaceutical company because of patentee Benitec's threats and litigation.

There is not one word about that in the opinion.

However, *MedImmune* specifically holds that declaratory judgment jurisdiction is not defeated where a putative infringer – by virtue of coercion resulting

from the patentee's threats – abstains from allegedly infringing activity that, if otherwise engaged in, would have supported jurisdiction, observing that:

> [jurisdiction exists] ***because the threat-eliminating behavior was effectively coerced*** . . . . The dilemma posed by that coercion – putting the challenger to the choice between abandoning his rights or risking prosecution – is "a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 152 (1967).

MedImmune, 127 S. Ct. at 772-73.

Again, Nucleonics has experienced this very type of coercion.

As Nucleonics' CEO Robert Towarnicki explained in his Declaration:

[REDACTED]

(App. 60a-61a at ¶14 – emphasis added). But for this coerced abstention from allegedly infringing activity, jurisdiction would exist based solely on that activity. Under *MedImmune*, jurisdiction still exists. The Federal Circuit was told of this but gave it no consideration and never performed the requisite *MedImmune* analysis.

* * * * *

The Federal Circuit's failure in this case to adhere to this Court's holdings in *Cardinal Chemical*, *Altvater* and *MedImmune*, if not corrected, will effectively serve as flawed precedent in countless cases[10]

> [b]ecause the Federal Circuit has exclusive jurisdiction over appeals from all United States District Courts in patent litigation, [and thus its decisions are] a matter of special importance to the entire Nation.

Cardinal Chemical, 508 U.S. at 89 (explaining why certiorari was granted). The result would be to undermine this Court's precedent and policy of policing invalid patents (especially those actually being asserted in litigation) via the Declaratory Judgment Act to the great detriment of countless innovating technology companies and the Nation as a whole.

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[10] *See supra* note 8.

CONCLUSION

For the reasons stated, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED JULY 20, 2007

UNITED STATES COURT OF APPEALS FEDERAL CIRCUIT

No. 06-1122.

BENITEC AUSTRALIA, LTD.,

Plaintiff-Appellee,

v.

NUCLEONICS, INC.,

Defendant-Appellant.

July 20, 2007.

Before RADER and DYK, Circuit Judges, and WHYTE, District Judge.*

Opinion for the court filed by District Judge WHYTE. Dissenting opinion filed by Circuit Judge DYK.

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* Honorable Ronald M. Whyte, District Judge, United States District Court for the Northern District of California, sitting by designation.

Appendix A

WHYTE, District Judge.

Nucleonics, Inc. ("Nucleonics") appeals from the judgment of dismissal for lack of subject matter jurisdiction entered by the United States District Court for the District of Delaware on Nucleonics's declaratory judgment counterclaims against Benitec Australia, Ltd. ("Benitec"). We affirm.

I. BACKGROUND

On March 22, 2004, Benitec sued Nucleonics for infringing U.S. Patent No. 6,573,099 ("'099 patent"), which relates to RNA-based disease therapy. Both parties are biotechnology companies that are engaged in gene silencing, which involves silencing the expression of disease-causing genes. A cell is exposed to a piece of foreign DNA that is specifically engineered to contain certain portions or copies of the target gene to be silenced. The foreign DNA then produces other molecules (double-stranded RNA) that shut down the expression of the target gene. This technology is known as RNA interference ("RNAi") gene silencing.

Nucleonics filed a timely answer to the complaint on March 24, 2004. On July 13, 2004, Nucleonics moved to dismiss Benitec's complaint and argued:

> Nucleonics now moves to dismiss Benitec's complaint for lack of jurisdiction and failure to state a claim upon which relief can be granted.... Simply stated, Benitec has shot

> before there is even a target. Nucleonics' accused activities are directed to developing and submitting information to the U.S. Food and Drug Administration . . . and are therefore exempt from infringement under 35 U . S . C . § 271(e)(1). . . .

Further, Nucleonics contended that:

> it [would] not be ready to file a New Drug Application to manufacture and market a new drug product until at least 2010-2012, if ever, depending on the progress of its clinical trials. . . . As a result, Benitec lacks a statutory basis to sue for infringement at this time, and it is premature for this Court even to entertain such a claim.

The court denied the motion, but without prejudice to reconsideration depending upon the outcome of the Supreme Court's review of *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed.Cir.2003).

On October 4, 2004, Nucleonics filed a request with the U.S. Patent and Trademark Office ("PTO") for

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1. Nucleonics filed a second request for reexamination on May 18, 2006. In both instances, the PTO ordered reexamination of the '099 patent. The PTO recently merged the two proceedings. Benitec canceled claims 1, 2, and 8 during the reexamination. In April 2006, the examiner rejected all other claims of the patent (Cont'd)

reexamination of the '099 patent.[1]

In 2005, Benitec encountered a pair of obstacles. First, Nucleonics received evidence indicating that the inventor named in the '099 patent may have misappropriated the idea for the invention from others, or at least should have named others as co-inventors on the patent application. On February 16, 2005, Nucleonics sought leave of court to amend its answer and add declaratory relief counterclaims of invalidity and unenforceability based upon alleged inventorship fraud. After some discovery skirmishes, Nucleonics obtained testimony in June 2005 from Australian scientists Peter Waterhouse and Ming-Bo Wang that they had contributed to the subject matter of the '099 patent. Neither, however, is named as an inventor in the '099 patent.

Second, and in the same month, the Supreme Court decided *Merck KGaA v. Integra Lifesciences I, Ltd.*, reading expansively the pharmaceutical research exception of § 271(e)(1). 545 U.S. 193, 125 S.Ct. 2372, 162 L.Ed.2d 160 (2005).

On August 1, 2005, Benitec moved to dismiss its complaint without prejudice under Federal Rule of Civil Procedure 41(a)(2). Benitec claims it sought dismissal

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(Cont'd)
in a non-final office action. In June 2006, Benitec submitted argument in an attempt to overcome the rejection, to which the examiner had not substantively responded as of December 13, 2006.

only because the *Merck* decision indicated that it had no presently viable infringement claim against Nucleonics. Nucleonics, on the other hand, claims Benitec sought dismissal in an attempt to prevent the district court from declaring the '099 patent invalid.

The district court granted Nucleonics's motion to amend its answer on September 14, 2005. Two weeks later, however, the court granted Benitec's motion to dismiss its complaint without prejudice and dismissed Nucleonics's counterclaims for lack of jurisdiction under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

During the time between the filing of Nucleonics's motion to amend to assert its counterclaims and the court's dismissal of those counterclaims, Nucleonics allegedly began discussing expanding its efforts beyond human health to animal husbandry and veterinary products.

Nucleonics appeals the dismissal of its declaratory judgment counterclaims. In its appellee's brief, Benitec "covenants and promises not to sue Nucleonics for patent infringement arising from activities and/or products occurring on or before the date dismissal was entered in this action-September 29, 2005."

The critical question on appeal is whether, in light of the circumstances, the court at this time has declaratory judgment jurisdiction over Nucleonics's counterclaims seeking declarations of invalidity and unenforceability of Benitec's '099 patent.

II. ANALYSIS

A. Developments Following Notice of Appeal

Subsequent to the oral argument in this case, the Supreme Court decided *MedImmune, Inc. v. Genentech, Inc.*, __ U.S. __, 127 S.Ct. 764, 166 L.Ed.2d 604 (2007). In view of that decision, particularly footnote 11 expressing disapproval of our previously used "reasonable apprehension of *imminent* suit" test for determining declaratory judgment jurisdiction,[2] we requested further briefing. The court has considered that briefing and is now also informed by this court's recent decisions in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330 (Fed.Cir.2007), and *SanDisk Corp. v. STMicroelectronics NV*, 480 F.3d 1372 (Fed.Cir.2007), both of which involve the application of the standards set forth in *MedImmune* for determining declaratory judgment jurisdiction.

B. Standard for Determining Declaratory Relief Jurisdiction

A party seeking to base jurisdiction on the Declaratory Judgment Act bears the burden of proving that the facts alleged, " 'under all the circumstances,

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2. The *MedImmune* Court noted that the "reasonable apprehension of imminent suit" test is an evolved form of the "reasonable apprehension of suit" test, which the Court also rejected.

show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.' " *MedImmune*, 127 S.Ct. at 771 (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273, 61 S.Ct. 510, 85 L.Ed. 826 (1941)). Prior to *MedImmune*, our case law required that there be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement *1344 suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *See, e.g., BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed.Cir.1993). However, "[t]he Supreme Court's opinion in *MedImmune* represents a rejection of our reasonable apprehension of suit test." *SanDisk*, 480 F.3d at 1380; *see also Teva*, 482 F.3d at 1339. In *MedImmune*, the Supreme Court held that in order for a court to have jurisdiction over a declaratory judgment action:

> the dispute be definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts. Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial

> controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

127 S.Ct. at 771 (internal citation and quotations omitted).

In *SanDisk*, we further explain:

> Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do. . . . We hold only that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights.

SanDisk, 480 F.3d at 1381. A useful question to ask in determining whether an actual controversy exists is what, if any, cause of action the declaratory judgment defendant may have against the declaratory judgment plaintiff:

Appendix A

> The concepts of "adverse legal rights" and "legal risk," used in [prior] cases to describe the standard for jurisdiction require that there be an underlying legal cause of action that the declaratory defendant could have brought or threatened to bring, if not for the fact that the declaratory plaintiff has preempted it. Without an underlying legal cause of action, any adverse economic interest that the declaratory plaintiff may have against the declaratory defendant is not a legally cognizable interest sufficient to confer declaratory judgment jurisdiction.

Microchip Tech. Inc. v. Chamberlain Group, Inc., 441 F.3d 936, 943 (Fed.Cir.2006).

The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since. *See Steffel v. Thompson*, 415 U.S. 452, 459 n. 10, 94 S.Ct. 1209, 39 L.Ed.2d 505 (1974); *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed.Cir.1995); *Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575 (Fed.Cir.1986). "If . . . a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction" at that time. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993). Further, once that burden has been met, *absent further information*, that

jurisdiction continues. *Id.* at 98, 113 S.Ct. 1967. The burden of bringing forth such further information may logically rest with the party challenging jurisdiction, *see id.* at 98, 113 S.Ct. 1967, but the actual burden of proof remains with the party seeking to invoke jurisdiction. *See Super Sack*, 57 F.3d at 1058; *Int'l Med. Prosthetics Research Assocs.*, 787 F.2d at 575. "The rule in federal cases is that an actual controversy must be extant at all stages of review, not merely at the time the complaint [was] filed." *Steffel*, 415 U.S. at 459 n. 10, 94 S.Ct. 1209.

The dissent's view that *Cardinal Chemical* holds that "the burden shifts to the party seeking to divest the court of jurisdiction to prove there is no longer a current case or controversy" reads more into the language of *Cardinal Chemical* than is justified. First, the Supreme Court makes clear at the outset of its opinion that "[the] practice [the Federal Circuit's uniform practice of declaring the issue of validity moot if it affirms the district court's finding of noninfringement], and the issue before us, therefore concern the jurisdiction of an intermediate appellate court-not the jurisdiction of either a trial court or this Court. In the trial court, of course, a party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy." 508 U.S. at 95, 113 S.Ct. 1967. Further, the Court only said that "[i]f a party to an appeal suggests that the controversy has, since the rendering of the judgment below, become moot, that party bears the *burden of coming forward* with subsequent events that have produced that alleged result." *Id.* at 98, 113 S.Ct. 1967 (emphasis added). The Court did not hold that the ultimate burden of proof in

the trial court was on other than the party seeking to invoke declaratory judgment jurisdiction.

With the basic principles for determining declaratory judgment jurisdiction in mind, we analyze the question of whether the court currently has declaratory judgment jurisdiction over Nucleonics's counterclaims.

C. Application of Standard for Declaratory Judgment Jurisdiction

1. Declaratory Judgment Jurisdiction Existed at the Time Nucleonics Filed it Counterclaims

At the time Nucleonics filed its counterclaims for declarations of invalidity and unenforceability, Benitec's patent infringement claims were pending. Because Nucleonics had been charged with infringement of the '099 patent, there was, as dictated by *Cardinal Chemical*, necessarily a case or controversy adequate to support jurisdiction at that time. *See id.*

2. Declaratory Judgment Jurisdiction at the Present Time

a. Human Application of RNAi

Cardinal Chemical, however, does not address whether subsequent events can divest the district court of jurisdiction, specifically here, over Nucleonics's

counterclaims. This court has rejected the argument that subsequent events cannot divest the trial court of jurisdiction, noting that *Cardinal Chemical* dealt primarily with this court's previous practice of vacating findings of patent invalidity as moot in light of non-infringement. *Super Sack*, 57 F.3d at 1060; *see also Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed.Cir.1999).

In *Super Sack*, we found that Super Sack's unconditional agreement "not to sue Chase for infringement as to any claim of the patents-in-suit based upon the products currently manufactured and sold by Chase" was sufficient to divest the court of jurisdiction over Chase's counterclaims for non-infringement, invalidity and unenforceability because Chase was engaged in no "*present activity*" placing it at risk of an infringement suit and Chase did not claim it was planning to make any new infringing product. 57 F.3d at 1059-60 (quoting *BP Chems.*, 4 F.3d at 978). We further explained that "[t]he residual possibility of a future infringement suit based on Chase's future acts is simply too speculative a basis for jurisdiction over Chase's counterclaim for declaratory judgments of invalidity." *Id.* at 1060.

In *Amana Refrigeration*, Amana sued Quadlux for "declaratory judgments of patent invalidity and noninfringement." 172 F.3d at 855. Quadlux responded with a promise not to sue Amana for patent infringement based on the patent-in-suit "as it presently reads, with respect to any product currently advertised,

manufactured, marketed or sold by Amana, or any product which was advertised, manufactured, marketed or sold by Amana prior to the date of" the promise. *Id.* We held that this promise divested the district court of jurisdiction, notwithstanding that at some indefinite point in the future, Amana might develop new products or the PTO might reissue the patent-in-suit with altered claims. *Id.* at 855-56.

Although neither *Super Sack* nor *Amana* has been expressly overruled, both applied the disapproved "reasonable apprehension of *imminent* suit" test. Therefore, although the holdings in both cases are not necessarily dependent on the "reasonable apprehension of imminent suit" requirement, we nevertheless base our analysis of whether jurisdiction currently exists over Nucleonics's declaratory judgment counterclaims strictly on the framework of *MedImmune.*

Nucleonics is currently researching applications of RNAi with an eye to treating human diseases, such as hepatitis B. Section 271(e)(1) of Title 35 of the United States Code provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using

> recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

The parties have now both taken the position that Nucleonics's present activities related to the human medical application of RNAi are, in light of § 271 and the Supreme Court's decision in *Merck*, not infringing and cannot become infringing until after Nucleonics files a new drug application ("NDA") with the U.S. Food and Drug Administration ("FDA"). Nucleonics took this position, which the dissent does not mention, even before the decision in *Merck*. Benitec acknowledged lack of infringement later when it moved to dismiss its infringement claims. Nucleonics does not even anticipate filing an NDA before "at least 2010-2012, if ever." Therefore, Nucleonics's activities of developing and submitting information to the FDA related to human application of RNAi does not present a case or controversy of sufficient immediacy and reality to warrant declaratory judgment jurisdiction over the enforceability of the '099 patent. The fact that Nucleonics may file an NDA in a few years does not provide the immediacy and reality required for a declaratory judgment. The situation is analogous to that in *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed.Cir.1992), where we affirmed the

district court finding that a defibrillator component manufacturer's claim for future patent infringement lacked a sufficient allegation of immediacy to support a declaratory judgment action since the potentially infringing defibrillator had only recently begun clinical trials and was years away from possible FDA approval.

Nucleonics argues that *Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340, 1342 (Fed.Cir.2005), supports its position that the court has jurisdiction. In *Fort James*, the plaintiff sued Solo Cup for infringement of three patents. Solo Cup "counterclaimed for declarations that the patents were invalid, unenforceable, and not infringed." *Id.* at 1343. The district court bifurcated the proceedings; all issues were to be tried to a jury first, except Solo Cup's unenforceability counterclaim, which was to be tried by the court following the jury trial. *Id.* at 1344. The jury found that one of the patents-in-suit was neither invalid nor infringed. *Id.* at 1345. Fort James then promised not to sue Solo Cup on any of the three patents for any product Solo Cup currently or previously manufactured and to "not seek to overturn the jury's verdict." *Id.* Solo Cup nonetheless wished to press forward with its declaratory claim for invalidity of one of the patents. *Id.* We held that there was still declaratory judgment jurisdiction over Solo Cup's counterclaim. *Id.* at 1349. The majority stated that Fort James's promise not to sue "had no effect on Fort James's claim for infringement, because that controversy had already been resolved by the jury's verdict." *Id.* at 1348. The majority concluded that "the jury verdict holding that Solo Cup did not infringe Fort

James's patents did not moot Solo Cup's counterclaim for unenforceability nor did it act to divest the district court of jurisdiction to hear that unlitigated counterclaim." *Id.*

Contrary to Nucleonic's assertions, *Fort James* does not compel jurisdiction here. The instant setting is different because no trial of the infringement issue has taken place. Benitec instead had its claims dismissed at its request before a trial and the considerable effort connected therewith had taken place. The court in *Fort James* distinguished *Super Sack* on this "unique procedural posture":

> In *Super Sack* and its progeny, the patentee's covenant not to sue was filed prior to consideration or resolution of the underlying infringement claim. In such circumstances, the promise not to sue obviated any reasonable apprehension that the declaratory judgment plaintiff might have of being held liable for its acts of infringement. . . . Here, however, the Post-Verdict Covenant had no effect on Fort James's claim for infringement, because that controversy had already been resolved by the jury's verdict.

Id. at 1348.

In *SanDisk*, we did hold that the statement of STMicroelectronics NV's ("ST") vice president of intellectual property and licensing that "ST has

absolutely no plan whatsoever to sue SanDisk" did not eliminate the justiciable controversy created by ST's actions. 480 F.3d at 1382. However, ST's statement was made when ST had engaged in a course of conduct that showed a willingness to enforce its patent rights despite its vice-president's statement. ST had approached SanDisk having made a studied and considered determination of infringement by SanDisk and having communicated that determination to SanDisk. It then only stated that it did not *intend* to sue SanDisk; it did not say it *would not* sue SanDisk in the future for its alleged infringement. *Id.* at 1382-83. In the instant case, Benitec made its covenant and sought dismissal of its infringement claim after it concluded that the *Merck* decision precluded an infringement claim based upon the activities of Nucleonics on which it, Benitec, had instituted its suit. Under these circumstances, there is no controversy between the parties concerning infringement by Nucleonics in its development of human applications of RNAi technology.

b. Animal Application of RNAi

Nucleonics now states, however, that it wishes to expand into animal RNAi products. Such products presumably would not be protected from infringement by § 271(e)(1) because they would appear to fall within its parenthetical exception to the safe harbor that excepts from infringement protection any "new animal drug or veterinary biological product . . . which is

primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques."

Nucleonics submitted to the district court the declaration of its president[3] who stated:

> Nucleonics wishes to expand its efforts beyond human health to animal husbandry and veterinary products. To this end, Nucleonics has entered into discussion with a large supplier of breeding stock for a variety of livestock food species regarding their needs and how RNA interference might be utilized to provide them a competitive advantage. These discussions began around May 25 of 2005; a meeting was held in Nashville on July 27. Nucleonics has executed a confidentiality agreement between the parties, which is a prerequisite to detailed technical discussions. Nucleonics expects work and research involving RNAi technology will commence shortly.

Nucleonics argues that the evidence offered by its president shows a justiciable case or controversy that supports declaratory judgment jurisdiction over its

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3. Benitec did not raise evidentiary objections to the declaration before the district court and therefore will not be heard to object now.

potential expansion to animal husbandry and veterinary products. To be liable as an infringer, Nucleonics must be one who "without authority makes, uses, offers to sell, or sells" a product that infringes the '099 patent. *See* 35 U.S.C. § 271(a). There was no evidence before the district court that Nucleonics had made or sold any infringing product.[4]

The meaning of "offer to sell" in § 271(a) is the offer of common law contracts. *Rotec Indus. v. Mitsubishi Corp.*, 215 F.3d 1246, 1254-55 (Fed.Cir.2000). The declaration of Nucleonics's president does not indicate that Nucleonics's desire to expand into animal markets has yet produced any definite offer which the unnamed "supplier of breeding stock" could accept. Nucleonics has not shown that it is engaged in any "use" of the patented invention that could subject it to an infringement suit by Benitec. Nucleonics has therefore not met its burden of showing that it is engaged in any present activity that could subject it to a claim of infringement by Benitec. *See Microchip Tech.*, 441 F.3d at 943. In other words, Nucleonics has not shown that its discussions regarding expansion into animal husbandry and veterinary products meet the immediacy and reality requirement of *MedImmune*. *See MedImmune*, 127 S.Ct. at 771.

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4. In fact, when Nucleonics moved for leave to file its counterclaims of invalidity and unenforceability on January 16, 2005, it apparently had not even begun discussions about expanding into animal husbandry and veterinary products.

Nucleonics has also failed to show that its future plans meet the immediacy and reality requirement of *MedImmune* necessary to support a justiciable controversy. Three reasons compel the conclusion that Nucleonics has not done so.

First, Nucleonics's only steps toward potentially-infringing animal research are discussions with an unnamed potential customer and execution of an undescribed confidentiality agreement. Nucleonics merely "expects" to begin work "shortly." We do not doubt the veracity of Nucleonics's president's statements-indeed, there is no evidence to the contrary. However, to allow such a scant showing to provoke a declaratory judgment suit would be to allow nearly anyone who so desired to challenge a patent.

Second, and particularly given the uncertain contours of § 271(e)(1), *see Merck*, 545 U.S. at 202, 125 S.Ct. 2372, Nucleonics has provided insufficient information for a court to assess whether Nucleonics's possible future animal work would be infringing or not. The Supreme Court in *Merck* held that § 271(e)(1) "exempted from infringement *all* uses of patented compounds 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs." 545 U.S. at 206, 125 S.Ct. 2372 (emphases in original). Although the allegedly infringing activity at issue in *Merck* did not implicate § 271(e)(1)'s parenthetical exception for animal drugs, here, based on the evidence Nucleonics has presented, one cannot

tell if Nucleonics intends to undertake activity that would fall within § 271(e)(1)'s parenthetical exception or would otherwise be infringing.

Third, although Benitec originally argued that animal testing for human use was infringing activity, it has now concluded that such testing falls within § 271(e)(1)'s protection. Benitec has never challenged use of the technology in testing in animals for animal use and claims another company owns any right to do so. In any event, there is no evidence of a justiciable controversy between Benitec and Nucleonics over Nucleonics's vaguely defined potential expansion to animal husbandry and veterinary products.

We recognize that Nucleonics would like to remove any concerns it or its potential investors might have over possible infringement of the Benitec patent. We do not express an opinion on whether Nucleonics's animal work could ever be the subject of an infringement suit. We merely hold that Nucleonics did not carry its burden of showing an existing justiciable controversy. As we observed in *Teva*:

> federal courts are to decide only actual controversies by judgment which can be carried into effect, and not to give opinions on moot questions or abstract propositions. . . . Although there can be a fine line between declaratory judgments and advisory opinions, the Supreme Court maintains the necessity of avoiding issuing advisory opinions on

hypothetical facts.

482 F.3d at 1338-39 (internal quotations and citation omitted). We also recognize that Nucleonics wishes to receive the benefit of a ruling on the validity and scope of Benitec's patent now, while Nucleonics undertakes any nascent animal work. There is currently, however, no "substantial controversy, between [Benitec and Nucleonics], of sufficient immediacy and reality to warrant the issusance of a declaratory judgment." *MedImmune*, 127 S.Ct. at 771. And there may never be.

III. CONCLUSION

Nucleonics has not made a showing of "sufficient

immediacy and reality" to support declaratory judgment jurisdiction. The district court's judgment of dismissal for lack of jurisdiction is affirmed.

AFFIRMED

DYK, Circuit Judge, dissenting.

If this declaratory judgment action were filed today, I would agree with the majority that the required case or controversy had not been established. I also agree that there must be a case or controversy at all stages of the litigation. *See Steffel v. Thompson*, 415 U.S. 452, 459 n. 10, 94 S.Ct. 1209, 39 L.Ed.2d 505 (1974). However, in my view, a different test for determining whether there is a case or controversy applies when the allegation of infringement is withdrawn during the course of litigation. Supreme Court precedent requires that, if a patentee files an infringement lawsuit and the particular claim of infringement is mooted, a counterclaim for invalidity should not be dismissed unless the patentee demonstrates that there is no possibility of a future controversy with respect to invalidity. *See Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 98, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993). In my view, Benitec made no such showing.

I

There is a strong public interest in permitting accused infringers to challenge invalid or unenforceable patents. *See Cardinal Chem.*, 508 U.S. at 100, 113 S.Ct.

1967; *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 345-47, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971); *Lear, Inc. v. Adkins*, 395 U.S. 653, 663-64, 89 S.Ct. 1902, 23 L.Ed.2d 610 (1969); *Altvater v. Freeman*, 319 U.S. 359, 364-65, 63 S.Ct. 1115, 87 L.Ed. 1450 (1943). The Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 (1934), plays an important role in facilitating such challenges, in particular by preventing patent holders from threatening enforcement while avoiding litigation that might render the patent invalid or unenforceable. *See Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed.Cir.1988). The Supreme Court in *MedImmune, Inc. v. Genentech, Inc.*, __ U.S. __, 127 S.Ct. 764, 166 L.Ed.2d 604 (2007), has recently emphasized the importance the Declaratory Judgment Act plays in protecting against the Hobson's choice of abandoning lawful endeavors or risking liability for infringement.[1] *Id.* at 772-73.

Here Benitec sued Nucleonics for infringement of

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1. The Advisory Committee Notes accompanying the 1937 adoption of Federal Rule of Civil Procedure 57 explain that

> [t]he controversy must necessarily be of a justiciable nature, thus excluding an advisory decree upon a hypothetical state of facts.... The existence or non-existence of any right, duty, power, liability, privilege, disability, or immunity or of any fact upon which such legal relations depend, or of a status, may be declared.

(internal quotation marks and citations omitted).

Benitec's patent, broadly alleging that Nucleonics is "engaged in making, using, offering to sell, and selling gene silencing technologies that are the same or equivalent to the technologies claimed in the Benitec patent." J.A. at 71. Nucleonics timely answered the complaint, denying infringement and, nearly ten months later, moved to add declaratory judgment counterclaims asserting invalidity and unenforceability. At the time of Nucleonics's counterclaim filing, it was clear that there was declaratory jurisdiction because "[i]f . . . a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction of a complaint, or a counterclaim, under the Act." *Cardinal Chem.*, 508 U.S. at 96, 113 S.Ct. 1967 (emphasis in original); *see also Arrowhead*, 846 F.2d at 736.

Nonetheless, the majority holds that when the accused infringer has been sued "[t]he burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since." Op. at 1344. In my view, the majority's approach erroneously applies the same standard for judging continuing declaratory jurisdiction as for judging original declaratory jurisdiction.

II

Here the patentee's manipulative efforts to defeat declaratory jurisdiction are clear enough. After Nucleonics moved to add the counterclaims, the Supreme Court decided *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 125 S.Ct. 2372, 162 L.Ed.2d 160 (2005), which addressed the 35 U.S.C. § 271(e)(1) safe harbor for research.[2] In *Merck*, the Supreme Court clarified that the safe harbor protects any research using a patented compound where the "drugmaker has a reasonable basis for believing that [the] patented compound may work ... to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA." *Merck*, 545 U.S. at 207, 125 S.Ct. 2372. The patentee does not claim that *Merck* provides any protection for commercial production of compounds for humans or production of or, even research for, animal compounds.

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2. Section 271(e)(1) provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product ... which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Appendix A

Following the *Merck* decision, Benitec, suggesting that it was unlikely to prevail on infringement claims directed to research on medical compounds for humans, filed a motion to dismiss the case without prejudice under Federal Rule of Civil Procedure 41(a)(2), asserting that there was no longer a continuing case or controversy. As the majority appears to recognize, op. at 1342-43, the motion may well have been motivated by a desire to avoid a patent invalidity determination.

Benitec did not offer a formal covenant not to sue before the district court. Rather, it stated in its motion to dismiss that it "could only bring new claims if Nucleonics is ultimately successful in obtaining FDA approval for its infringing products or otherwise engages in infringing activities not otherwise permitted under the § 271(e) exemption." J.A. at 1379. Nucleonics

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3. Nucleonics submitted the declaration of Robert J. Towarnicki, Nucleonics's president and CEO, stating that:

> Nucleonics wishes to expand its efforts beyond human health to animal husbandry and veterinary products. To this end, Nucleonics has entered into discussion with a large supplier of breeding stock for a variety of livestock food species regarding their needs and how RNA interference might be utilized to provide them a competitive advantage. These discussions began around May 25 of 2005; a meeting was held in Nashville on July 27. Nucleonics has executed a confidentiality agreement between the parties, which is a prerequisite to detailed technical discussions. Nucleonics expects work and research involving RNAi technology will commence shortly. J.A. at 1412.

opposed the motion to dismiss on several grounds, including that there was a continuing controversy because it had taken "concrete steps . . . with the intent to conduct" allegedly infringing activity, including research on drugs for animals. *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed.Cir.1993).[3] The district court granted the motion to dismiss without prejudice finding that, although "Nucleonics has demonstrated a reasonable apprehension of suit," it "has not demonstrated that it has produced or has prepared to produce a product that would be the target of an infringement lawsuit by Benitec." *Benitec Austl. Ltd. v. Nucleonics, Inc.*, No. 04-0174, slip op. at 6-8, 2005 WL 2415959 (D.Del. Sept. 29, 2005).

Nucleonics filed this appeal, arguing that Benitec's statement was insufficient to eliminate declaratory jurisdiction. In an effort to defeat jurisdiction, Benitec expanded its representation, stating that its argument to the district court included-and was intended to include-a promise "not to sue Nucleonics for patent infringement arising from activities and/or products occurring on or before the date dismissal was entered in this action-September 29, 2005." Appellee's Br. 45. At oral argument, Benitec again purported to clarify its covenant. Benitec stated that it would not sue "for any research that was going on prior to the dismissal" or "for animal research that was done at the time of the dismissal." Notably, Benitec offered no covenant with respect to future human or animal products or animal research.

The majority holds that Nucleonics has the burden

of demonstrating a continuing case or controversy as narrowed by Benitec's promises. Op. at 1344. It concludes that Nucleonics has not met this burden as to either its human application of RNAi or its animal application of RNAi. Op. at 1347, 1349. In my view, the majority applies an erroneous test.

III

The Supreme Court has clearly established that once declaratory jurisdiction has been established, the burden shifts to the party seeking to divest the court of jurisdiction to prove that there is no longer a current case or controversy. *See Cardinal Chem.*, 508 U.S. at 98, 113 S.Ct. 1967. In *Cardinal Chemical*, we initially held that a finding of non-infringement moots a declaratory counterclaim for invalidity. *Id.* at 87, 113 S.Ct. 1967. The Supreme Court reversed finding that "it is perfectly clear that the District Court had jurisdiction to entertain Cardinal's counterclaim" because "if . . . a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction of a complaint, or a counterclaim, under the Act." *Id.* at 96, 113 S.Ct. 1967 (emphasis in original). The Court explained that while the initial burden of establishing declaratory judgment jurisdiction rests on the party seeking a declaratory judgment, "once that burden has been met courts are entitled to presume, absent further information, that jurisdiction continues." *Id.* at 98, 113 S.Ct. 1967.

In explaining the policy reasons for shifting the burden, the Court stated that "[a] company once charged with infringement must remain concerned about the risk of similar charges if it develops and markets similar products in the future." *Id.* at 99-100, 113 S.Ct. 1967. Moreover, declining jurisdiction over invalidity counterclaims "creates [the] potential for relitigation and imposes ongoing burdens on competitors who are convinced that a patent [is] invalid." *Id.* at 101, 113 S.Ct. 1967; *see also Textron Lycoming Reciprocating Engine Div., Avco Corp. v. United Auto., Aerospace and Agric. Implement Workers of Am.*, 523 U.S. 653, 660, 118 S.Ct. 1626, 140 L.Ed.2d 863 (1998) ("[T]he only question is whether the parties had any concrete dispute over the contract's voidability *at the time the suit was filed.*" (emphasis added)). Nothing in the Supreme Court's recent *MedImmune* decision, __U.S. __, 127 S.Ct. 764, 166 L.Ed.2d 604, suggests that the same test for determining whether a case or controversy exists applies throughout the lawsuit.

The majority distinguishes *Cardinal Chemical* as resting on the fact that at the time of the alleged mootness the case was on appeal after a judgment of non-infringement, but there is nothing in the Supreme Court's decision that restricts its burden-shifting holding to that limited context. Op. at 1345. Contrary to the majority, *Cardinal Chemical* cannot be limited to

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4. *See, e.g., Liquid Dynamics v. Vaughan Co., Inc.*, 355 F.3d 1361, 1371 (Fed.Cir.2004) ("A district court judge faced with an invalidity counterclaim challenging a patent that it concludes was (Cont'd)

mootness at the court of appeals level. If a case is not moot when the case is on appeal, it can hardly be moot in identical circumstances at the district court level. Our decisions holding that *Cardinal Chemical* does not compel a district court to decide an invalidity counterclaim after entering a judgment of non-infringement are best understood as recognizing district court discretion under the Declaratory Judgment Act.[4] Indeed, in repeatedly recognizing that a district court may decide the invalidity issue after a judgment of non-infringement, we have confirmed that such cases are not moot in the Article III sense of the term.

In any event, this is not a case in which the patentee suffered an adverse judgment, but rather one in which it voluntarily abandoned its infringement suit in the light of unfavorable developments. It is particularly inappropriate to place the burden of establishing continuing jurisdiction on declaratory plaintiffs where, as here, the claim of mootness is the result of the opposing party's acts designed, at least in part, to defeat declaratory jurisdiction. "[T]here is an important public interest in protecting the legal system against manipulation by parties, especially those prone to involvement in repeat litigation, who might contrive to

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(Cont'd)

not infringed may either hear the claim or dismiss it without prejudice, subject to review only for abuse of discretion."); *see also Cardinal Chemical*, 508 U.S. at 95 n. 17, 113 S.Ct. 1967 ("[T]he Declaratory Judgment Act affords the district court some discretion in determining whether or not to exercise that jurisdiction, even when it has been established.").

moot cases that otherwise would be likely to produce unfavorable precedents." Hart and Wechsler, *The Federal Courts and the Federal System* 204 (5th ed.2003); *see also Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha*, 57 F.3d 1051, 1053 (Fed.Cir.1995) ("[O]ne who may become liable for infringement should not be subject to manipulation by a patentee who uses careful phrases in order to avoid explicit threats, thus denying recourse to the courts while damages accrue.").

In the closely related injunction context, the Supreme Court has repeatedly held that the defendant carries a heavy burden of demonstrating that a case is moot when it voluntarily ceases the accused conduct. As the Supreme Court noted in *Iron Arrow Honor Society v. Heckler*, 464 U.S. 67, 72, 104 S.Ct. 373, 78 L.Ed.2d 58 (1983), "[d]efendants face a heavy burden to establish mootness in such cases because otherwise they would simply be free to 'return to [their] old ways' after the threat of a lawsuit had passed.... Thus they must establish that 'there is no reasonable likelihood that the wrong will be repeated.' " (quoting *United States v. W.T. Grant Co.*, 345 U.S. 629, 632, 73 S.Ct. 894, 97 L.Ed. 1303 (1953)); *see also Public Serv. Co. of Colo. v. Shoshone-*

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5. *See also Buckhannon Bd. & Care Home v West Virginia Dep't Health and Human Res.*, 532 U.S. 598, 609, 121 S.Ct. 1835, 149 L.Ed.2d 855 (2001) (stating that "[i]t is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice" unless it is "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur").

Bannock Tribes, 30 F.3d 1203, 1206 n. 3 (9th Cir.1994). Similarly in *Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 189, 120 S.Ct. 693, 145 L.Ed.2d 610 (2000), the Supreme Court again concluded that "[t]he heavy burden of persuading the court that the challenged conduct cannot reasonably be expected to start up again lies with the party asserting mootness." (internal quotation marks omitted).[5] *Cardinal Chemical* confirms that the same rule governs in the declaratory context and requires a showing by the patentee that there is no reasonable likelihood that the controversy over the patent's validity and enforceability will recur.

IV

In my view, the patentee here has not come close to meeting its burden to show that there will be no future controversy. Even if we were to assume that there is no longer any possible controversy concerning Nucleonics's research on human drugs, there is a possibility that Nucleonics may in the future make human drugs that Benitec would challenge as infringing. Nucleonics has also stated that it intends to pursue animal research. While I agree with the majority that the future controversy would not satisfy the sufficient immediacy and reality test for the filing of a new suit today, Benitec has made no effort to demonstrate that the controversy between the parties will not recur. In fact, when asked at oral argument whether Benitec was "promising not to sue [Nucleonics] for animal product research that they begin" the day after argument, Benitec's counsel

responded, "We have not made that statement that we would forebear suing them." Here Benitec's success in defeating declaratory jurisdiction will have the effect of inhibiting Nucleonics's ability to raise funds and conduct research and development. Nucleonics has stated that the threat of litigation has "hampered its efforts to obtain funding and to continue its business activities." Appellant's Br. 45 n. 19. Benitec has not satisfied its burden to eliminate any future controversy concerning infringement of the '099 patent.

V

The majority's decision here is not only inconsistent with the Supreme Court precedent; it exposes an inconsistency in this court's own jurisprudence. We have twice previously addressed the question of continuing declaratory jurisdiction in suits for infringement where the patent holder has attempted to defeat continuing jurisdiction by a covenant not to sue. *See Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340 (Fed.Cir.2005); *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054 (Fed.Cir.1995). As the majority recognizes, op. at 1345-46, those cases rested on our now-rejected reasonable apprehension test, and may no longer be good law after *MedImmune*, 127 S.Ct. at 774 n. 11. But assuming that they are still good law, they in fact conflict with each other.

In *Super Sack*, 57 F.3d 1054, we held that a covenant not to sue defeated jurisdiction, though we noted that the accused infringer "never contended that it ha[d] taken meaningful preparatory steps toward an infringing activity by planning to make a new product that may later be said to infringe," and that "[t]he

residual possibility of a future infringement suit based on [the accused infringer's] future acts is simply too speculative a basis for jurisdiction over [the] counterclaim for declaratory judgments of invalidity." *Id.* at 1059-60.[6] In *Fort James*, 412 F.3d 1340, even though the accused infringer did not prove a controversy that would satisfy the sufficient immediacy and reality test, we held the opposite-that a covenant not to sue for existing products did not render the declaratory claim moot, even though there was no evidence of a future controversy. *Id.* at 1348. While the majority here attempts to reconcile the two cases on the ground that the covenant in *Super Sack* came before a judgment of non-infringement, whereas in *Fort James* it came after a judgment of non-infringement, I fail to see why this should make any difference, nor did the dissent in *Fort James* itself. *See id.* at 1354 (Schall, J., dissenting).

VI

The effect of today's decision is to limit the availability of declaratory jurisdiction to challenge invalid and unenforceable patents by allowing patentees to moot such controversies by dismissing the original infringement action and covenanting not to bring suit on existing products, without any showing that the controversy will not recur in the future. I respectfully dissent.

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6. In *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed.Cir.1999), we applied the same test to a covenant not to sue filed after the commencement of a declaratory action where no infringement action had been commenced.

APPENDIX B — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE DATED SEPTEMBER 29, 2005

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

No. Civil Action No. 04-0174 JJF

BENITEC AUSTRALIA LTD.,

Plaintiff,

v.

NUCLEONICS, INC.,

Defendant.

MEMORANDUM OPINION

FARNAN, District Judge

Pending before the Court is the Motion For Voluntary Dismissal Without Prejudice (D.I.108) filed by Plaintiff, Benitec Australia, Ltd. ("Benitec").[1] For the reasons discussed, the Court will grant Benitec's motion.

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1. Defendant Nucleonics, Inc. filed an Unopposed Motion And Supporting Memorandum To File A Surreply In Opposition To Plaintiff's Motion For Voluntary Dismissal Without Prejudice (D.I.117). The Court will grant the Motion, and the Surreply will be deemed filed.

Appendix B

BACKGROUND

The parties are engaged in conducting research and developing technologies to create therapeutics to treat disease using gene silencing technologies. On March 22, 2004, Benitec filed its Complaint (D.I.1), alleging that Defendant, Nucleonics, Inc. ("Nucleonics"), infringes U.S. Patent No. 6,573,099 ("the '099 patent").

On February 16, 2005, Nucleonics files a Motion To Amend Its Answer to add seven declaratory judgment counterclaims of non-infringement, patent invalidity under 35 U.S.C. § 102, patent invalidity under 35 U.S.C. § 103, patent invalidity under 35 U.S.C. § 112(1), patent invalidity under 35 U.S.C. § 112(2), patent invalidity under 35 U.S.C. § 116, and patent unenforceability. (D.I.91). On September 14, 2005, the Court issued an Order granting Nucleonics' Motion To Amend Its Answer (D.I.119).

The parties have not yet completed discovery.

PARTIES' CONTENTIONS

By its motion, Benitec contends that this case should be dismissed without prejudice pursuant to Federal Rule of Civil Procedure 41(a) because of a substantive change in the law with regard to the scope of the exemption set forth in 35 U.S.C. § 271(e)(1). Specifically, Benitec contends that the recent decision of the United States Supreme Court in *Merck KGAA v. Integra Lifesciences I, Ltd.*, 125 S.Ct. 2372 (2005), had the effect of negating

the case or controversy before the Court with regard to infringement of Benitec's patents and, therefore, dismissal is warranted.

In response, Nucleonics contends that the Court retains jurisdiction to decide its counterclaims for invalidity, unenforceability, and non-infringement because Nucleonics has a reasonable apprehension of being sued by Benitec in the future. Nucleonics argues that, because Benitec filed a lawsuit for patent infringement against Nucleonics and Benitec has not provided Nucleonics with a covenant not to sue for past, present, and future acts, jurisdiction over the declaratory judgment counterclaims exists.

LEGAL STANDARD

When a plaintiff moves for a dismissal without prejudice under Rule 41(a)(2), the decision to dismiss with prejudice or without is left to the discretion of the court. *Buse v. Vanguard Group of Inv. Co.*, No. 91-3560, 1994 WL 111359, at *2 (E.D. Pa Apr. 1 1994). Specifically, Rule 41(a)(2) provides: "[A]n action shall not be dismissed at the plaintiff's instance save upon order of the court and upon such terms and conditions as the court deems proper. If a counterclaim has been pleaded by a defendant . . . the action shall not be dismissed against the defendant's objection unless the counterclaim can remain pending for independent adjudication by the court. Unless otherwise specified in the order, a dismissal under this paragraph is without prejudice." Fed.R.Civ.P. 41(a)(2) (2004). A Rule 41(a)(2) motion "will be

determined after attempting to secure substantial justice to both parties." *DuToit v. Strategic Minerals Corp.*, 136 F.R.D. 82 (D.Del.1991) *citing Lunn v. United Aircraft Corp.*, 26 F.R.D. 12, 14 (D.Del.1960). Moreover, while considering the legitimate interests of both parties, the Court must bear in mind that a plaintiff's motion should be granted absent substantial prejudice to the defendant. *Id.* at 10.

DISCUSSION

The Court concludes that dismissing Benitec's action would not cause substantial prejudice to Nucleonics because no actual controversy supports jurisdiction under the Declaratory Judgment Act for Nucleonic's declaratory judgment claims against Benitec.

Nucleonics objects to dismissing Benitec's action without prejudice because Nucleonics contends that Benitec's action "brought a public cloud of uncertainty" over Nucleonics. (D.I. 110 at 2.) Thus, Nucleonics contends that Benitec should not now be allowed to leave the playing field, keeping its patent safe from scrutiny with regard to invalidity or unenforceability, while continuing to taint Nucleonic's current and future business and technology with the threat of another lawsuit. Nucleonics argues that the Declaratory Judgment Act, 28 U.S.C. § 2201, permits the Court to independently adjudicate Nucleonics' counterclaims.

The Declaratory Judgment Act "requires an actual controversy between the parties before a federal court

may exercise jurisdiction over an action for a declaratory judgment." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed.Cir.1996). Nucleonics has the burden of establishing the existence of an actual case or controversy. *See Cardinal Chemical Co. v. Morton Intern., Inc.*, 508 U.S. 83, 95 (1993). When a party has actually been charged with infringement of a patent, there is, necessarily, a case or controversy adequate to support jurisdiction of a counterclaim pursuant to the Declaratory Judgment Act. *Id.* at 96. Furthermore, a counterclaim questioning the validity or enforceability of a patent raises issues beyond the initial claim for infringement. *Id.* The issue before the Court, then, is whether an actual controversy sufficient to support the Court's jurisdiction over Nucleonics' declaratory judgment counterclaims continues to exist if Benitec's patent infringement claim is dismissed.

Benitec contends that dismissing its infringement claim divests the Court of jurisdiction to hear the counterclaims. However, a number of courts have held that withdrawing a charge of infringement will not necessarily preclude the existence of an actual controversy, especially if, as here, the withdrawal occurs after the filing of the declaratory judgment action. *See, e.g., C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 881 (Fed.Cir.1983); *Societe de Conditionnement v. Hunter Eng'g*, 655 F.2d 938 (9th Cir.1981). In turn, Nucleonics contends that, because Benitec has refused to enter into a covenant not to sue for enforcement of the '099 patent against Nuceonics at a later time, an actual controversy necessarily exists. However, a patentee's refusal to

promise not to enforce the patent, while "relevant to the [actual controversy] determination," is "not dispositive." *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 980 (Fed.Cir.1993).

In the alternative, Nucleonics contends that it has a reasonable apprehension of suit because Benitec has already sued Nucleonics and others for patent infringement, Benitec has not promised not to assert the '099 patent against Nucleonics in the future, and Benitec has requested a voluntary dismissal of its action without prejudice. In reply, Benitec contends that Nucleonics has nothing to fear because Nucleonics' research activities are exempt from infringement liability pursuant to § 271(e)(1) and the Supreme Court's decision in *Integra.*

The test for determining whether an actual case or controversy exists in a declaratory judgment action involving patents is two-pronged. First, the defendant's conduct must have created on the part of the plaintiff a reasonable apprehension that the defendant will initiate suit if the plaintiff continues the allegedly infringing activity. Second, the plaintiff must actually have either produced the product or have prepared to produce that product. *Indium Corp. v. Semi-Alloys, Inc.*, 781 F.2d 879 (Fed.Cir.1985)

With regard to the first prong, the Court concludes that Nucleonics has demonstrated a reasonable apprehension of suit. The factual background in this case is such that Nucleonics could be concerned that Benitec would, at some time, file a patent infringement suit

against it. By suing Nucleonics and alleging that Nucleonics' technology is now covered by the Benitec's patent, Benitec has engaged in a course of conduct that shows a willingness to protect that technology. *See, e.g., C.R. Bard v. Schwartz*, 716 F.2d 874, 880-81 (Fed.Cir.1983); *Int'l Medical Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575, 229 U.S.P.Q. 278, 281 (Fed.Cir.1986)

With regard to the second prong, production or preparation of a product, Nucleonics contends that its entire research effort is devoted to the RNAi area of technology and its activities will ultimately leave the safe harbor created by *Integra*. Nucleonics further alleges that it anticipates beginning research on livestock diseases, which are unprotected by the safe harbor. In response, Benitec argues that future infringement is not ripe for adjudication because Benitec's product may never be approved by the FDA or may be approved in a form that does not implicate the claims of the '099 patent. (D.I. 115 at 18.)

The declaratory judgment plaintiff carries the burden of proving the existence of facts underlying its allegations of the existence of an actual controversy. *Jervis B. Webb Co.*, 742 F.2d 1388, 1399 (Fed.Cir.1984). On the record before it, the Court concludes that Nucleonics has not demonstrated that it has produced or has prepared to produce a product that would be the target of an infringement lawsuit by Benitec. At the time this lawsuit was filed, Nucleonics was several years away from obtaining FDA approval. Further, as argued by

Benitec, there is no certainty that any product approved by the FDA would be the same product that was in clinical trials at the time this lawsuit was filed. And finally, Nucleonics has adduced no evidence that it has undertaken sales or marketing activity with regard to any product. For these reasons, he Court concludes that any threat of litigation that may have existed now lacks sufficient immediacy and reality to support declaratory judgment jurisdiction.

CONCLUSION

In the circumstances presented here, the Court concludes that no actual controversy supports jurisdiction under the Declaratory Judgment Act for Nucleonic's declaratory judgement claims against Benitec with regard to the '099 patent. Accordingly, the Court will grant Benitec's Motion For Voluntary Dismissal Without Prejudice (D.I.108).

An appropriate Order will be issued.

Appendix B

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

No. Civil Action No. 04-0174 JJF

BENITEC AUSTRALIA LTD.,

Plaintiff,

v.

NUCLEONICS, INC.,

Defendant.

ORDER

At Wilmington, this 29th day of September 2005, for the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that:

1. The Motion For Voluntary Dismissal Without Prejudice (D.I.108) filed by Plaintiff, Benitec Australia, Ltd. is ***GRANTED***.

2. Defendant Nucleonics, Inc.'s Unopposed Motion And Supporting Memorandum To File A Surreply In Opposition To Plaintiff's Motion For Voluntary Dismissal Without Prejudice (D.I.117) is ***GRANTED***.

Appendix B

3. The Surreply attached as Exhibit 1 to the Unopposed Motion And Supporting Memorandum To File A Surreply In Opposition To Plaintiff's Motion For Voluntary Dismissal Without Prejudice (D.I.117) is deemed filed.

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED JANUARY 20, 2007

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

06-1122

BENITEC AUSTRALIA, LTD.,

Plaintiff-Appellee,

v.

NUCLEONICS, INC.,

Defendant-Appellant.

Before RADER and DYK, Circuit Judges , and WHYTE,* District Judge.

ORDER

On January 9, 2007, the Supreme Court decided *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. __. While MedImmune dealt primarily with the issue of whether declaratory judgment jurisdiction exists over issues of patent validity, enforceability, and infringement even though the declaratory plaintiff is a licensee of the

* Honorable Ronald M. Whyte, United States District Court for the Northern District of California, sitting by designation.

patent in good standing, the Court also dealt more broadly with the standard for declaratory jurisdiction. In that connection, the Court expressed its disapproval of the "reasonable apprehension of imminent suit" test:

> Even if *Altvater* could be distinguished as an "injunction" case, it would still contradict the Federal Circuit's "reasonable apprehension of suit" test (or, in its evolved form, the "reasonable apprehension of imminent suit" test, *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F. 3d 1324, 1333 (2005)). A licensee who pays royalties under compulsion of an injunction has no more apprehension of imminent harm than a licensee who pays royalties for fear of treble damages and an injunction fatal to his business. The reasonable-apprehension-of-suit test also conflicts with our decisions in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U. S. 270, 273 (1941), where jurisdiction obtained even though the collision-victim defendant could not have sued the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured; and *Aetna Life Ins. Co. v. Haworth*, 300 U. S. 227, 239 (1937), where jurisdiction obtained even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit. It is also in tension with *Cardinal Chemical Co. v. Morton Intl, Inc.*, 508 U. S. 83, 98 (1993), which held

> that appellate affirmance of a judgment of noninfringement, eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent inva'idity.

Slip. Op. at 13 n.11.

The court invites supplemental briefing in light of the Supreme Court's decision in *MedImmune*. The supplemental briefing should assume familiarity with the background facts of the case and be focused solely on the effect, if any, *MedImmune* has on this appeal. The briefs and other materials already filed remain before the court.

Appellant's supplemental brief, of no more than ten double-spaced pages in length, shall be filed within thirty days of the date of filing of this order. Appellee's brief, of no more than ten double-spaced pages in length, shall be filed within twenty days after service of the Appellant's brief. Any reply brief, up to five double-spaced pages in length, shall be filed within ten days thereafter. The parties are to file an original and eleven copies of each brief, and serve two copies on opposing counsel.

FOR THE COURT

s/ Jan Horbaly
Jan Horbaly
Clerk

January 10, 2007
Date

APPENDIX D — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT FILED OCTOBER 4, 2007

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

06-1122

BENITEC AUSTRALIA, LTD.,

Plaintiff-Appellee,

v.

NUCLEONICS, INC.,

Defendant-Appellant.

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellant, and a response thereto having been invited by the court and filed by the Appellee, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en bane and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

Appendix D

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on October 11, 2007.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 10/04/2007

APPENDIX E — ANNUAL REPORT

Letter from the Chairman

* * *

Intellectual Property

Several years before the global scientific community accepted the reality of RNAi in mammalian cells, Benitec was the first to show the universality of RNAi by demonstrating the down-regulation of target gene expression in human and mammalian cells, inventing a reliable means of triggering the RNAi process using DNA constructs. Benitec's core patents are based on this early research and are supported by subsequent filings that extend the scope and jurisdiction of its IP and the utility of his technology.

Benitec's patent estate represents a dominant position in DNA-directed gene silencing, and potentially the dominant position in RNAi applications for humans and mammals. On June 4 and 5, 2003, the first US and UK patents for the application of RNA interference to mammalian cells were awarded in Benitec.

* * * *

APPENDIX F — NEWS — BENITEC LEADER IN GENE SILENCING TECHNOLOGY DATED DECEMBER 2, 2004

BENITEC ANNOUNCES LITIGATION STATUS

2 December 2004

* * *

Benitec commenced proceedings against Nucleonics, Inc. in March of 2004 as they were obviously infringing on Benitec's issued patent estate, of which Nucleonics was aware. Benitec was advised that Nucleonics was in the process of raising in excess of U.S. $40 million from U.S. investors using Benitec's ddRNAi technology, which was the subject of an issued patent in the United States dated June 2003. Benitec thought it necessary and important to bring to the attention of the prospective investors in Nucleonics the existence of Benitec's issued patents and to ensure that Benitec could not be criticized at a later date of having known of infringement, but of having taken no action to protect Benitec's intellectual property, or the interests of Nucleonics' own investors.

* * * *

APPENDIX G — BENITEC'S OPPOSITION TO NUCLEONICS' MOTION TO DISMISS BENITEC'S CLAIM AND TO STAY ALL UNRELATED DISCOVERY DATED JULY 27, 2004

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Civil Action No. 04-174-JJF

CONFIDENTIAL – FILED UNDER SEAL

BENITEC AUSTRALIA LTD.,
an Australian corporation,

Plaintiff,

v.

NUCLEONICS INC., a Delaware corporation;
AMBION, INC., a Delaware corporation; and
GENSCRIPT CORPORATION,
a Delaware corporation,

Defendants.

BENITEC'S OPPOSITION TO NUCLEONICS' MOTION TO DISMISS BENITEC'S CLAIM AND TO STAY ALL UNRELATED DISCOVERY

* * *

Appendix G

B. Nucleonics' Infringing Activities

[*REDACTED*]

APPENDIX H — EXCERPTS FROM THE AUSTRALIAN HAGUE CONVENTION TESTIMONY TAKEN ON JUNE 3 AND JUNE 8, 2005

* * *

TESTIMONY OF MING-BO WANG

[REDACTED]

Appendix H

[*REDACTED*]

TESTIMONY OF DR. PETER WATERHOUSE

[*REDACTED*]

APPENDIX I — DECLARATION OF ROBERT J. TOWARNICKI DATED AUGUST 15, 2005

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Civil Action No. 04-174-JJF

BENITEC AUSTRALIA LTD.,

Plaintiff,

v.

NUCLEONICS, INC., a Delaware corporation,

Defendant.

DECLARATION OF ROBERT J. TOWARNICKI

[*REDACTED*]

Appendix I

[*REDACTED*]

Appendix I

[*REDACTED*]

Appendix I

[*REDACTED*]

Appendix I

[*REDACTED*]

Appendix I

[REDACTED]

Appendix I

[*REDACTED*]

s/ Robert J. Towarnicki
ROBERT J. TOWARNICKI

88

FILED
MAR 20 2008
OFFICE OF THE CLERK
SUPREME COURT, U.S.

[REDACTED]

No. 07-1068

IN THE
Supreme Court of the United States

NUCLEONICS, INC.,
Petitioner,

v.

BENITEC AUSTRALIA, LTD.,
Respondent.

On Petition For A Writ Of Certiorari To The United States Court of Appeals For The Federal Circuit

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Federal Circuit correctly found, based on the particular facts of this case, that speculative future infringement that may never materialize does not support declaratory judgment jurisdiction?

2. Whether the Federal Circuit correctly found, based on the particular facts of this case, that jurisdiction over declaratory judgment claims ended with patentee's covenant not to sue for infringement, when the covenant was made before the District Court had tried the case or issued any decision on the merits?

RULE 29.6 STATEMENT

Benitec Australia, Ltd. is 100% owned by Benitec UK, Ltd., which is 100% owned by Benitec Limited, a public company listed on the Australian Securities Exchange.

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CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1).

STATEMENT OF THE CASE

A. Introduction

This case presents a unique procedural and factual posture that does not warrant granting certiorari. The Federal Circuit has correctly applied the precedents of this Court relating to declaratory judgment jurisdiction to the facts of this case. Simply put, there is no case or controversy currently existing between the parties.

While the petition suggests that Benitec Australia, Ltd. ("Benitec") brought suit for testing in mice and rabbits (Pet. 5-6), it fails to admit that

these activities were asserted by Nucleonics, Inc. ("Nucleonics") to be animal testing for human therapeutic use, as opposed to animal therapeutic use or testing for animal therapeutic use. As explained below, Benitec owns the rights to animal testing for human use but a non-party to this lawsuit owns the rights to animal testing for animal use.

B. The Parties, Patent, and Technology

The petition incorrectly characterizes the respondent as a patent "troll." Pet. 8. In fact, Benitec is a biotechnology company engaged in developing technologies to treat serious diseases and advancing medical research using gene silencing technologies. *Benitec Austl. Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1342 (Fed. Cir. 2007) ("*Benitec*"), Pet. App. 2a. *See also* J.A. 70-71 ¶¶ 2, 9.[1] Benitec's work involves human therapeutic use of double-stranded RNA ("dsRNA" or "ddRNA"), often referred to as interference RNA ("iRNA"). Human therapeutic use of iRNA is covered by the claims of the patent-in-suit, U.S. Patent No. 6,573,099 ("the '099 Patent"). The '099 Patent also covers use of iRNA in animals other than humans. J.A. 68-69.

The ownership as well as the rights to practice the '099 Patent are currently divided between Benitec and Australian non-party Commonwealth Scientific and Industrial Research Organization ("CSIRO"), with each holding a discrete bundle of rights. J.A. 1528-52.

---

[1] References to "J.A." are to the Confidential Joint Appendix submitted to the Federal Circuit on June 13, 2006.

Specifically, Benitec has the exclusive right to commercialize the '099 Patent in the "Human Field," which includes the use of the technology in humans and any use of the technology in animal research for testing the technology for human use. J.A. 1530 at (B)(a); J.A. 1536 ¶ 2.2; J.A. 1532(a-c). In contrast, CSIRO has the exclusive right to commercialize the '099 Patent in non-human fields, including the "Animal Field," which includes use of the technology in animals and testing in animals for animal use. J.A. 1530 at (B)(b); J.A. 1536 ¶ 3; J.A. 1530-31(a-h).

Benitec also has the right to sublicense its human therapeutic use and animal testing for human use, but the right to sublicense the use of the technology in the Animal Field belongs exclusively to CSIRO. J.A. 1536-37 ¶ 4.3. Thus, Benitec has exclusive patent rights relating to humans, while CSIRO has exclusive rights in the animal field.

Nucleonics, Inc. ("Nucleonics")

REDACTED

REDACTED

On April 1, 2004, long after the issuance of the '099 Patent, Nucleonics announced that it had raised $49.2 million in venture capital financing to pursue therapeutic use of iRNA. J.A. 2748-49. *See also* J.A. 1410 ¶ 11.

C. Proceedings Below

1. District Court Proceedings

On March 22, 2004, Benitec sued Nucleonics for infringement of the '099 Patent. Benitec had filed suit against Nucleonics as its competitor for human therapeutic use of iRNA and had argued that animal testing for human use was infringing activity.

Nucleonics' April 30, 2004 answer to the complaint did not include any counterclaims. J.A. 75-78.

On July 13, 2004, Nucleonics moved to dismiss the action for lack of jurisdiction based on 35 U.S.C. § 271(e)(1), asserting that all of its activities, including animal-related activities, would fall within the safe harbor. *Benitec*, 495 F.3d at 1342, Pet. App. 2a-3a. Nucleonics unambiguously represented to the District Court and Benitec that "Benitec has shot before there is even a target" because "Nucleonics' accused activities are directed to developing and submitting information to the [FDA] and are therefore exempt from infringement under [§ 271(e)(1)]." *Id.* at 1342, Pet App. 2a-3a. *See also* J.A. 2656. Nucleonics further asserted that "Benitec lacks a statutory basis to sue for infringement at this time, and it is premature for this Court even to entertain such a claim.

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[2] The FDA must approve an IND before clinical trials (*i.e.*, human testing) can be conducted.

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In support of its motion, Nucleonics submitted declarations by Dr. Satishchandran, Nucleonics' co-founder and Vice President for Research and Development. J.A. 2666-76, J.A. 2798-801. Dr. Satishchandran averred that:

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Thus, Nucleonics repeatedly represented to the District Court and Benitec that all of its work fell within the scope of the § 271(e) safe harbor. Throughout discovery, Nucleonics maintained this position and never sought to supplement its discovery responses with the position it now embraces in an attempt to defeat dismissal in the District Court. Neither the Federal Circuit dissent nor Nucleonics' petition to this Court mention Nucleonics' motion or declaration.

Benitec's opposition to Nucleonics' motion to dismiss relied primarily upon the Federal Circuit's decision in *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003) ("*Integra*"), *vacated*, 545 U.S. 193 (2005). J.A. 2696-702. The Federal Circuit had held that pre-clinical

experiments to screen and identify potential new drug candidates did not qualify for safe harbor protection under § 271(e)(1). In deciding that pre-clinical research is not exempt from infringement, the Federal Circuit held that "[t]he safe harbor does not reach any exploratory research that may rationally form a predicate for future FDA clinical tests." *Integra*, 331 F.3d at 867. Thus, the Federal Circuit held that the safe harbor exemption did not reach back down the research chain to protect the earliest stages of screening and research for potential drug candidates. *Id.* at 867.

Based on the Federal Circuit's subsequently-overruled *Integra* decision, Benitec had argued that Nucleonics' research activities extended beyond the scope of the § 271(e)(1), and thus were not protected by the safe harbor exemption. The District Court agreed and denied Nucleonics' motion to dismiss on February 7, 2005. J.A. 2850. The District Court noted, however, that "the Supreme Court may possibly reverse the Federal Circuit's holding in *Integra*". *Id.* Accordingly, the court denied Nucleonics' motion "with leave to renew in the event the *Integra* case is reversed." *Id.* *See also Benitec*, 495 F.3d at 1342, Pet. App. 3a.

On February 16, 2005, Nucleonics sought leave to file an amended answer, which for the first time included a counterclaim seeking declaratory judgment that the '099 Patent was invalid and unenforceable. J.A. 252-65. The District Court granted Nucleonics leave on September 14, 2005. J.A. 23.

On June 13, 2005, this Court decided *Merck KGaA v. Integra Lifesciences I, Ltd.*, which vacated

the Federal Circuit's *Integra* ruling and clarified the broad range of activities that § 271(e)(1) exempts from infringement. 545 U.S. 193, 207 (2005) ("*Merck*"). In view of *Merck* and the District Court's prior ruling, on August 1, 2005, Benitec moved to dismiss the case without prejudice pursuant to Fed. R. Civ. P. 41(a)(2). J.A. 1373-74. Benitec explained that, in light of this Court's decision and Nucleonics' previous representations to the District Court,

> Benitec could only bring new claims if Nucleonics is ultimately successful in obtaining FDA approval for its infringing products or otherwise engages in infringing activities not otherwise permitted under the § 271(e) exemption. Nucleonics' original motion, which the [District] Court indicated it would reconsider if the law were changed by [this Court's decision in the] *Integra* case, is essentially a motion for dismissal for lack of jurisdiction because there can be no case or controversy if the § 271(e)(1) exemption applies. There is no basis for this Court to dismiss with prejudice infringement claims that do not yet exist. Accordingly, Benitec respectfully requests that the Court dismiss this case without prejudice.

J.A. 1379. Benitec's reply reiterated that it "has no basis to continue to assert its claims." J.A. 1508 (emphasis added).

Despite the unambiguous nature of the statements Nucleonics made to the District Court in its own motion to dismiss on the same § 271(e)(1) grounds, Nucleonics opposed Benitec's motion for

dismissal and made self-contradictory statements. In support of its opposition, Nucleonics filed a declaration of its President and CEO, Robert Towarnicki ("Towarnicki"). J.A.1408-13. Towarnicki asserted that Nucleonics "wishes" to expand its business to include animal husbandry and veterinary products, and that Nucleonics has had "discussions" with an unknown breeding stock supplier. *Benitec*, 495 F.3d at 1348, Pet. App. 18a. *See also* J.A. 1412 ¶ 20. There is, however, no other evidence in the record regarding Nucleonics' "wishes" or the nature and scope of any such discussions.

Towarnicki also asserted that Nucleonics had "signed an agreement" with a "pharmaceutical" company to work on an "exploratory collaboration". Nucleonics' "Petition For Rehearing And Rehearing En Banc", filed August 3, 2007, *available at* 2007 WL 2434249, ("Pet. for Reh'g") at 4. *See also* J.A. 1410-11. As with Nucleonics' vague "discussions", there is no other evidence in the record regarding the nature, scope, or progress of any such "exploratory collaboration", nor is there any explanation of how such work with a "pharmaceutical" company could possibly fall outside of the protection of the 35 U.S.C. § 271(e)(1) safe harbor.

The District Court granted Benitec's motion on September 29, 2005. *Benitec Austl. Ltd. v. Nucleonics, Inc.*, 2005 U.S. Dist. Lexis 22008 (D. Del. Sept. 29, 2005), Pet. App. 36a-45a. Nucleonics appealed.

Benitec represented to the Federal Circuit that "[t]o the extent that there is any ambiguity in the record, Benitec's motion [to dismiss] included — and

was intended to include — a promise not to sue Nucleonics for patent infringement arising from activities and/or products occurring on or before the District Court's September 29, 2005 dismissal order...." Non-Confidential Brief Of Plaintiff-Appellee Benitec Australia, Ltd., filed April 27, 2006, *available at* 2006 WL 1433923, at 12 (citation omitted). *See also Benitec*, 495 F.3d at 1343, Pet. App. 5a. Thus, Benitec has unconditionally covenanted not to sue Nucleonics for patent infringement arising from activities and/or products occurring on or before the date dismissal was entered in this action — September 29, 2005.[3] *See Sierra Applied Sciences, Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1375-76 (Fed. Cir. 2004) (statements by attorney in colloquy with the District Court, in Federal Circuit brief, and at oral argument constituted a promise to forebear from suing).

After this Court issued *MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764 (2007), both parties

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[3] To the extent that Nucleonics complains that Benitec's covenant does not include a covenant not to sue for the

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Nucleonics has never withdrawn these sworn declarations and it is most reasonable to presume they are still correct. Moreover, Benitec could not include the rights for animal use in animal therapeutics in its covenant not to sue because it neither owns nor controls these rights, which are owned by CSIRO. J.A. 1528-52; A1530 at (B)(b); J.A. 1530-31(a-h); J.A. 1536-37 ¶ 4.3. *See, e.g., Pope Mfg. Co. v. Gormully & Jeffery Mfg. Co.*, 144 U.S. 248, 250 (1892).

filed supplemental briefs on that decision with the Federal Circuit.

2. Federal Circuit Affirmance

The Federal Circuit affirmed the District Court's dismissal in an opinion that followed this Court's precedent, despite Nucleonics' attempts to mischaracterize it.

The Federal Circuit recognized that if "'a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction' at that time." *Benitec*, 495 F.3d at 1344; Pet. App. 9a, (quoting *Cardinal Chem. Co. v. Morton Int'l*, 508 U.S. 83, 96 (1993)). Nucleonics' assertion that "the majority gave no further credence to *Cardinal Chemical*" regarding jurisdiction (Pet. 13) is incorrect. The Federal Circuit recognized that "once that burden [of establishing jurisdiction] has been met, *absent further information*, that jurisdiction continues." *Benitec*, 495 F.3d at 1344-45; Pet. App. 9a-10a (citing *Cardinal*, 508 U.S. at 98).

The Federal Circuit further noted that "'[i]f a party to an appeal suggests that the controversy has, since the rendering of the judgment below, become moot, that party bears the *burden of coming forward* with subsequent events that have produced that alleged result.'" *Benitec*, 495 F.3d at 1345, Pet. App. 10a (quoting *Cardinal*, 508 U.S. at 98; emphasis added by Federal Circuit). The Federal Circuit then addressed the fact-intensive events subsequent to the filing of this litigation that have divested jurisdiction. *Benitec*, 495 F.3d at 1345-49, Pet. App. 11a-22a.

Nucleonics also incorrectly alleges that the Federal Circuit's analysis of whether any of Nucleonics' asserted activities supported jurisdiction was "except in name, a clear return to the disapproved 'reasonable apprehension of imminent lawsuit' test." Pet. 28. Nucleonics ignores the fact that in *MedImmune*, this Court held that for declaratory judgment jurisdiction to exist, the dispute must be "definite and concrete"; "real and substantial"; and of "*sufficient immediacy and reality* to warrant the issuance of a declaratory judgment." *MedImmune*, 127 S. Ct. at 771 (emphasis added). In accordance with *MedImmune*, the Federal Circuit assessed whether Nucleonics' asserted activities had "sufficient immediacy and reality" to present a case or controversy. *See, e.g., Benitec*, 495 F.3d at 1346, 1348-49, Pet. App. 14a, 19a-20a, 22a-23a.

Nucleonics' petition for rehearing and petition for rehearing *en banc* was denied.

3. USPTO Reexamination

On October 4, 2004, Nucleonics initiated a third party reexamination of the '099 Patent at the U.S. Patent and Trademark Office ("USPTO"). *Benitec*, 495 F.3d at 1342, n.1, Pet. App. 3a-4a, n.1. On May 18, 2006, Nucleonics requested a second reexamination of the '099 Patent. *Id.* On October 26, 2006, the USPTO merged these two reexaminations, and they are still pending. *Id.*; U.S. Reexamination Nos. 90/007,247 and 90/008,096 (*see http://portal.uspto.gov/external/portal/pair*).

In its first reexamination request, Nucleonics claimed that the '099 Patent was invalid for alleged indefiniteness and lack of written description and

provided the USPTO with art that Nucleonics asserted invalidated the '099 Patent. J.A. 1616-17. Nucleonics' second request added more art that it asserted invalidated the patent. U.S. Reexamination No. 90/008,096.

Although the USPTO issued rejections of the claims over art provided by Nucleonics, the USPTO did not base any rejections on Nucleonics' claims of indefiniteness or lack of written description. U.S. Reexamination Nos. 90/007,247 and 90/008,096. Benitec has responded to all rejections and has cancelled claims. *Id.* The merged reexamination proceeding is still pending. *Id.*

REASONS FOR DENYING THE PETITION

This case presents no issue meriting the Court's attention. First, the Federal Circuit's decision in this case is intricately bound to an unusual, complicated, and disputed set of facts. Thus, the decision lacks the broad import attributed to it by Nucleonics. Second, the decision does not conflict with any decisions of this Court. Third, the Federal Circuit's decision correctly applied the law to the unusual posture of this case.

A. The Decision Is Intricately Bound To An Unusual, Complicated, And Disputed Set Of Facts And Lacks Broad Applicability.

Nucleonics' assertions of the importance of the opinion in this case "to defendants in every patent infringement suit" is absurd in view of the fact-dependant nature of the opinion. The Federal Circuit's opinion did not set forth any broad or original pronouncements of law, even in dicta.

Rather, the opinion consists of (a) a detailed exploration of the facts, including the existence of relevant factual issues that are not resolved because the facts were not provided to the District Court or are not yet in existence and (b) application of existing law of this Court and the Federal Circuit to the specific facts. The Federal Circuit based its jurisdictional decision on the following specific factors:

- Benitec moved to dismiss its claims before any trial or decision on infringement (*Benitec*, 495 F.3d at 1343, 1347-48, Pet. App. 4a-5a, 16a-17a);
- Benitec covenanted not to sue Nucleonics based on activities that had already occurred (*Benitec*, 495 F.3d at 1343, 1347-48, Pet. App. 5a, 17a);
- Nucleonics was not presently engaging in any potentially infringing activity, and its plans for future potentially infringing activity were not definite or concrete (*Benitec*, 495 F.3d at 1346-47, 1348-50, Pet. App. 13a-15a, 17a-21a);
- after Benitec filed suit, this Court clarified the § 271(e)(1) safe harbor such that it became evident that Nucleonics' only current or imminent activities of any commercial interest to Benitec are shielded from claims of infringement (*Benitec*, 495 F.3d at 1342, 1349, Pet. App. 4a, 20a-22a);
- before Benitec moved to dismiss the case for lack of jurisdiction, Nucleonics had moved to dismiss on the same grounds (*Benitec*, 495 F.3d at 1342, Pet. App. 2a-3a); and

- the patent-at-issue is currently being reexamined (*see, e.g.*, *Benitec*, 495 F.3d at 1342, n.1, Pet. App. 3a-4a, n.1) and may emerge with different claims.

The impact of the Federal Circuit opinion has likewise been limited. In cases citing *Benitec* in which the intellectual property owner sued for infringement or could otherwise have been characterized as asserting its intellectual property at the time of filing of the suit in question, then successfully sought to have counterclaims challenging its intellectual property dismissed for lack of jurisdiction, either the intellectual property owner provided a covenant not to sue that satisfied the court that there was no longer any case or controversy, the intellectual property owner had filed a formal statutory disclaimer with the USPTO (thereby, prohibiting any suit for infringement of the disclaimed patent), or the court found that the party seeking a declaratory judgment had not shown current, or concretely-planned future, possibly infringing activity. *See Monsanto Co. v. Syngenta Crop Prot., Inc.*, 2008 U.S. Dist. Lexis 7236 (E.D. Mo. Jan. 31, 2008) (finding both that patent owner's conduct did not show willingness and preparedness to enforce its patent and that declaratory plaintiff did not show current or planned infringing activity); *Vantage Trailers, Inc. v. Beall Corp.*, 2008 U.S. Dist. Lexis 7133 (S.D. Tex. Jan. 31, 2008); *Furminator, Inc. v. Kim Laube & Co.*, 2008 U.S. Dist. Lexis 1105 (E.D. Mo. Jan. 7, 2008); *Pfizer Inc. v. Ranbaxy Labs.*, 525 F. Supp. 2d 680 (D. Del. 2007); *Merck & Co. v. Apotex, Inc.*, 2007 U.S. Dist. Lexis 84426 (D.N.J. Nov. 15, 2007); *MMJK, Inc. v. Ultimate Blackjack*

Tour LLC, 2007 U.S. Dist. Lexis 85502 (N.D. Cal. Nov. 7, 2007); *Furminator, Inc. v. Ontel Prods. Corp.*, 246 F.R.D. 579 (E.D. Mo. 2007); *Abbott Labs. v. Baxter Healthcare Corp.*, 2007 U.S. Dist. Lexis 76449 (N.D. Ill. Sept. 28, 2007); *Crossbow Tech., Inc. v. YH Tech.*, 2007 U.S. Dist. Lexis 65646 (N.D. Cal. Aug. 21, 2007).

In cases citing *Benitec* in which the intellectual property owner sued for infringement or could otherwise have been characterized as asserting its intellectual property at the time of filing of the suit in question, and did not provide a satisfactory covenant or disclaimer, the District Courts retained jurisdiction. *Boston Sci. Corp. v. Johnson & Johnson Inc.*, 2008 U.S. Dist. Lexis 5510 (D. Del. Jan. 24, 2008); *Cordance Corp. v. Amazon.com, Inc.*, 521 F. Supp. 2d 340 (D. Del. 2007); *Sabert Corp. v. Waddington N. Am., Inc.*, 2007 U.S. Dist. Lexis 68092 (D.N.J. Sept. 14, 2007); *FieldTurf USA, Inc. v. Sports Constr. Group, LLC*, 507 F. Supp. 2d 801 (N.D. Ohio 2007). *See also Teva Pharm. Indus. v. Reddy's Labs.*, 2008 U.S. Dist. Lexis 16958 (D.N.J. Mar. 4, 2008) (denying summary judgment motion for lack of case or controversy as to claim for which patentee provided covenant not to sue, but denying summary judgment motion on the merits without prejudice to refile as to claim for which no covenant was provided); *MedImmune, Inc. v. Genentech, Inc.*, 2008 U.S. Dist. Lexis 12198 (C.D. Cal. Feb. 7, 2008) (granting motion to dismiss claims for declaratory judgment of invalidity and unenforceability of patent claims as to which patentee provided covenant not to sue, but retaining jurisdiction over claims for

declaratory judgment on patent claim as to which no covenant was provided).

The Federal Circuit's other decisions applying *MedImmune* illustrate that it is correctly applying this Court's precedent and also that jurisdiction is found to exist in the majority of cases. In the nine cases other than *Benitec* in which the Federal Circuit applied *MedImmune* to determine whether jurisdiction existed, it found that jurisdiction was lacking in only one. *Maxwell v. Stanley Works, Inc.*, 2008 U.S. App. Lexis 323 (Fed. Cir. Jan. 8, 2008). In seven cases, the Federal Circuit found that jurisdiction did exist, although it found that discretionary dismissal had been proper in one of these (*Cellco*) and might be proper on remand in another (*Sony*). *Micron Tech., Inc. v. Mosaid Techs.*, Inc., 2008 U.S. App. Lexis 4387 (Fed. Cir. Feb. 29, 2008); *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364 (Fed. Cir. 2007); *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982 (Fed. Cir. 2007); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007); *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007); *Cellco P'ship v. Broadcom Corp.*, 227 Fed. Appx. 889 (Fed. Cir. 2007); *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271 (Fed. Cir. 2007). In one case, the court did not determine whether jurisdiction existed, but vacated and remanded for consideration in light of *MedImmune*. *Baker Hughes Oilfield Operations, Inc. v. Reedhycalog UK, Ltd.*, 228 Fed. Appx. 988 (Fed. Cir. 2007).

Indeed, a finding of jurisdiction in this case would improperly open all patent holders, whether

licensing the patent or not, to expansive threats of declaratory judgment action for mere patent ownership. Nucleonics essentially argues that present activities that do not infringe and undefined, hypothetical future activities can support jurisdiction under the Declaratory Judgment Act. Adopting Nucleonics' standard would confer jurisdiction to nearly anyone abstaining from any contemplated action, no matter how theoretical or remote in time, because they feared they might someday be sued for infringement. Thus, it is the result desired by Nucleonics that would result in grave and widespread harm — to every patent owner.

B. Nucleonics' Petition Seeks To Broaden Declaratory Judgment Jurisdiction To Obtain An Unconstitutional Advisory Opinion.

Article III jurisdiction is limited to the resolution of cases and controversies. *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 471 (1982); *Sierra Applied Sciences*, 363 F.3d at 1372; *Travelers Ins. Co. v. Obusek*, 72 F.3d 1148, 1153-54 (3d Cir. 1995). The requirement for the existence of a case or controversy is not relaxed in cases under the Declaratory Judgment Act. *See Obusek*, 72 F.3d at 1153.

A controversy "must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Aetna Life Ins.*

Co. v. Haworth, 300 U.S. 227, 241 (1937). "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941). Here, the degree of immediacy and reality required to create jurisdiction is not present. This fact-specific finding does not convert this case into one of Constitutional importance.

An action or counterclaim brought under the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, may not be used to obtain an advisory opinion on a hypothetical state of facts. *Calderon v. Ashmus*, 523 U.S. 740, 746 (1998); *Obusek*, 72 F.3d at 1153-54 ("The existence of a 'case or controversy' is a condition precedent to the proper exercise of judicial power by a federal court and the Declaratory Judgment Act can not relax that constitutional requirement."); *Arrowhead Indus. Water v. Ecolochem*, 846 F.2d 731, 736 (Fed. Cir. 1988) (A declaratory plaintiff is not entitled to "an advisory opinion on whether it would be liable for patent infringement if it were to initiate some merely contemplated activity."), *overruled in part by MedImmune*, 127 S. Ct. at 774 n.11 (rejecting Federal Circuit's use of "reasonable-apprehension-of-suit test"). Nucleonics' attempt to obtain an advisory opinion when there is insufficient immediacy and reality to support a declaratory judgment action should be rejected, and the petition for certiorari should be denied.

Additionally, a party wishing to challenge the validity of a patent is not without recourse if it cannot establish declaratory judgment jurisdiction: it may file a reexamination of the patent in the USPTO and even participate in it. In fact, that is precisely what Nucleonics has done here. On October 4, 2004, Nucleonics initiated a third party Reexamination challenging the validity of the '099 Patent. On May 18, 2006, Nucleonics requested yet another reexamination of the '099 Patent. *Benitec*, 495 F.3d at 1342, n.1, Pet. App. 3a-4a, n.1. On October 26, 2006, the USPTO merged these two reexaminations, and they are still pending. *Id.*; U.S. Reexamination Nos. 90/007,247 and 90/008,096 (*see http://portal.uspto.gov/external/portal/pair*). Thus, the claims with which the '099 Patent will emerge from reexamination are not known.

C. The Federal Circuit's Decision Does Not Conflict With *Cardinal* or *Altvater*.

The Federal Circuit's analysis recognized that if "'a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction' at that time." *Benitec*, 495 F.3d at 1344, Pet. App. 9a (quoting *Cardinal*, 508 U.S. at 96). It further recognized that "once that burden [of establishing jurisdiction] has been met, *absent further information*, that jurisdiction continues." *Benitec*, 495 F.3d at 1344-45, Pet. App. 9a-10a (citing *Cardinal*, 508 U.S. at 98). The Federal Circuit also noted that "'[i]f a party to an appeal suggests that the controversy has, since the rendering of the judgment below, become moot, that party bears the

burden of coming forward with subsequent events that have produced that alleged result.'" *Benitec*, 495 F.3dat 1345, Pet. App. 10a (quoting *Cardinal*, 508 U.S. at 98; emphasis added by Federal Circuit).

Cardinal recognized that a change in circumstances can divest jurisdiction: "[i]f, before the court had decided the case, either party had advised it of a material change in circumstances that entirely terminated the party's controversy, it would have been proper either to dismiss the appeal or to vacate the entire judgment of the District Court." 508 U.S. at 98. *See also id.* at 97 (If "[the Federal Circuit] had jurisdiction while the case was pending before it, the case remains alive (*barring other changes*) when it comes to us.") (emphasis added); *United States v. Munsingwear*, 340 U.S. 36, 39 (1950) (a case that becomes moot should be reversed or vacated and remanded for dismissal); *Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974) (an "actual controversy must be extant at all stages of review, not merely at the time the complaint is filed.").

In the instant case, there were material changes in circumstances that entirely terminated the controversy. Specifically, (1) this Court's holding in *Merck*, in combination with (2)

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and that it did not plan to seek FDA approval to manufacture and market a prospective drug product until at least 2012, if ever (3) as a result, Nucleonics' activities could not be found to be infringing, and (4) Benitec covenanted not to sue Nucleonics for any activities before the date that District Court dismissed the suit.

Further, the Federal Circuit's determination that *Cardinal* "did not hold that the ultimate burden of proof in the trial court was on other than the party seeking to invoke declaratory judgment jurisdiction" (*Benitec*, 495 F.3d at 1345, Pet. App. 10a-11a) is fully in accord with this Court's decision in *Cardinal*. By its own terms, *Cardinal* is limited to circumstances where a party is seeking to vacate a judgment. *See, e.g., Cardinal*, 508 U.S. at 100 ("the burden of demonstrating that changed circumstances provide a basis for *vacating the judgment* of patent invalidity rests on the party that seeks such action") (emphasis added); *id.* at 95 (The "issue before [this Court in *Cardinal* concerned] the jurisdiction of an intermediate appellate court — *not the jurisdiction of either a trial court or this Court. In the trial court, of course, a party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy.*") (emphasis added).

As the Federal Circuit had previously recognized:

> The question actually before the Supreme Court in *Cardinal* was "whether the affirmance by the Court of Appeals for the Federal Circuit of a finding that a patent has not been infringed is a sufficient reason," by itself, "for vacating a declaratory judgment holding the patent invalid." [*Cardinal*, 508 U.S. at 85]. The Court answered in the negative, but noted "that factors in an unusual case might justify [the Federal Circuit's] refusal to reach the merits of a validity determination," *id.* at [102], making the decision a relatively narrow one. In other

> words, according to *Cardinal*, a claim for a declaratory judgment of invalidity is independent of the patentee's charge of infringement in the following — and only the following — way: an affirmed finding of noninfringement does not, without more, justify a reviewing court's refusal to reach the trial court's conclusion on invalidity.

Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1060 (Fed. Cir. 1995), *overruled in part by MedImmune*, 127 S. Ct. at 774 n.11 (rejecting Federal Circuit's use of "reasonable-apprehension-of-suit test").[4]

Thus, *Cardinal* did not hold or even suggest that "the ultimate burden of proof in the trial court was on other than the party seeking to invoke declaratory judgment jurisdiction." *Benitec*, 495 F.3d at 1345, Pet. App. 10a-11a. *Cardinal* did not even make any such statement in dicta.

The Federal Circuit properly found that *Cardinal* does not apply to District Court jurisdiction, particularly where that Court has not rendered any judgment on the merits. *Cardinal* states that the consideration perhaps "most important is the interest of the successful litigant in preserving the value of a declaratory judgment that... 'it obtained on a valid counterclaim at great effort and expense.'" 508 U.S. at 99 (quoting *Morton Int'l v. Cardinal Chem.*, 967 F.2d 1571, 1577 (Fed. Cir. 1992) (Nies, C.

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[4] Although *MedImmune* rejected the "reasonable-apprehension-of-suit test" (127 S. Ct. at 774 n.11), the rejected test was not used to support *Super Sack*'s finding regarding the applicability of *Cardinal*.

J., dissenting from denial of rehearing en banc). *Cardinal* also decried "the wasteful consequences of relitigating the validity of a patent after it has once been held invalid in a fair trial" occasioned by routinely vacating judgments of invalidity. *Id.* at 100-01. *See also Super Sack*, 57 F.3d at 1060 (where, as in the instant case, "the trial court neither made a finding on infringement nor reached a conclusion on validity[,] *Cardinal*, addressed to the propriety of appellate jurisdiction over final judgments respecting infringement and validity, simply does not apply.") This particular rationale for the *Cardinal* decision has no relevance to cases, such as the instant case, in which there is no successful litigant, there is no judgment on the merits, and there has been no trial.

Nor is the Federal Circuit's decision in conflict with *Altvater v. Freeman*. 319 U.S. 359 (1943). In *Altvater*, the District Court decided the case on the merits, finding non-infringement and invalidity, but the Eighth Circuit vacated the invalidity decision on the basis that the non-infringement ruling had mooted the counterclaims. *Id.* at 362-63. This Court reversed and remanded. *Id.* at 365-66. Unlike in the instant case, the *Altvater* declaratory plaintiff's claims were not moot because there was no intervening event between filing and judgment on the merits — such as a covenant not to sue — that divested the court of jurisdiction. Here, there were intervening events.

D. The Federal Circuit's Decision Does Not Conflict With *MedImmune*

Nucleonics alleges that the Federal Circuit's analysis of whether any of Nucleonics' asserted activities supported jurisdiction was "except in name, a clear return to the disapproved 'reasonable apprehension of imminent lawsuit' test." Pet. 28. Nucleonics ignores the fact that in *MedImmune*, this Court held that for declaratory judgment jurisdiction to exist, the dispute must be "definite and concrete"; "real and substantial"; and of "*sufficient immediacy and reality* to warrant the issuance of a declaratory judgment." *MedImmune*, 127 S. Ct. at 771 (emphasis added). In accordance with *MedImmune*, the Federal Circuit properly assessed whether Nucleonics' asserted activities had "sufficient immediacy and reality" to present a case or controversy. *See, e.g., Benitec*, 495 F.3d at 1346, 1348-49, Pet. App. 14a, 19a-20a, 22a-23a.

Nucleonics, in alleging that its asserted vague "wishes" and potential future activities support jurisdiction to challenge the validity of claims of a patent that may emerge from reexamination with substantially different claims, would remove the long-standing requirements for immediacy and reality from the case or controversy requirement. *See, e.g., Haworth*, 300 U.S. at 241 (a controversy "must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts."); *Arrowhead Indus.*, 846 F.2d at 736 (declaratory plaintiff not entitled to "an

advisory opinion on whether it would be liable for patent infringement if it were to initiate some merely contemplated activity."). Even the Federal Circuit dissent agreed that: "[i]f this declaratory judgment action were filed today... the required case or controversy had not been established" and "the future controversy would not satisfy the sufficient immediacy and reality test for the filing of a new suit today...." *Benitec*, 495 F.3d at 1350, 1354, Pet. App. 23a, 33a.

Significantly, in *MedImmune* itself, the threat of harm avoided by petitioner's continuing royalty payments would otherwise have been "*imminent*". 127 S. Ct. at 772 (emphasis added). Thus, the teaching of *MedImmune* is that declaratory judgment jurisdiction exists when "Petitioner's own acts... eliminate the *imminent* threat of harm." *Id.* (emphasis added). In the instant case, Nucleonics is simply not faced with "'imminent' injury in fact fairly... trace[able] to" any concrete action by Benitec. *Id.* at 772 n.8 (citation omitted).

For Nucleonics' activities prior to the District Court's dismissal of the suit, Benitec's covenant not to sue destroyed any "substantial controversy" between the parties. Based on the facts of this case, including the scant and hypothetical information provided to the Court by Nucleonics, Nucleonics' later activities are not "definite and concrete" or "real and substantial" enough and are not of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 127 S. Ct. at 771; *Benitec*, 495 F.3d at 1346, 1348-49, Pet. App. 14a, 19a-20a, 22a-23a.

1. Nucleonics' Activities Related To Human Use Do Not Support Jurisdiction.

In its motion to dismiss, Nucleonics itself represented that

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J.A. 2662. *See also* J.A. 2659, J.A. 2661-63.

After *Merck* was decided by this Court, Benitec recognized that Nucleonics was exempt from infringement under 35 U.S.C. § 271(e)(1). *See, e.g.*, J.A. 1379. As the Federal Circuit stated, Benitec and Nucleonics "have now both taken the position that Nucleonics' present activities related to the human medical application of RNAi are, in light of § 271 and the Supreme Court's decision in *Merck*, not infringing and cannot become infringing until after Nucleonics files a new drug application ('NDA')...." *Benitec*, 495 F.3d at 1347, Pet. App. 14a. *See also id.*, 495 F.3d at 1342, Pet. App. 3a (Nucleonics

asserted that an NDA will not be filed until at least 2010-12); J.A. 2663. Thus, Nucleonics' activities reasonably related to human use of RNAi, including animal testing, are exempt from current infringement liability and will be exempt for many years.

The record does not support any showing that a controversy of sufficient immediacy and reality exists between Benitec and Nucleonics. Nucleonics may never file an NDA, and any product or technique approved by the FDA may not come within the scope of the claims of the '099 Patent. This is particularly true since a reexamination of the '099 Patent is pending. *See, e.g.*, *Benitec*, 495 F.3d at 1342, n.1, Pet. App. 3a-4a, n.1. It is therefore not known what, if any, claims may exist by the time Nucleonics may file an NDA. Indeed, even Nucleonics admits that it may be many years until it files an NDA. Accordingly, any controversy regarding Nucleonics' human applications of RNAi lacks the requisite reality and immediacy to support declaratory judgment jurisdiction.

2. Nucleonics' Purported Wish To Expand Its Efforts Does Not Support Jurisdiction.

After Benitec moved to dismiss, Nucleonics asserted for the first time that it "wishes to expand its efforts beyond human health to animal husbandry[,]"and had "executed a confidentiality agreement" as a "prerequisite to detailed technical discussions" for possible work. *Benitec*, 495 F.3d at 1348, Pet. App. 18a. *See also* J.A. 1412 ¶ 20. This vague wish does not create jurisdiction. The

described activity is largely speculative, describing generally what might someday happen. Further, as properly found by the Federal Circuit, the concrete acts that Nucleonics did describe do not constitute infringement under 35 U.S.C. § 271(a). *Benitec*, 495 F.3d at 1348-49, Pet. App. 17a-21a. *See, e.g., Rotec v. Mitsubishi*, 215 F.3d 1246, 1254-55 (Fed. Cir. 2000).

Even if Nucleonics does eventually engage in activity within the scope of current or reexamined claims, § 271(e)(1) would likely exempt them, in view of

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and (2) the wide breadth of activities that are protected: § 271(e)(1) "exempt[s] from infringement *all* uses of patented compounds 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs." *Merck*, 545 U.S. at 206. *See also id.* at 208 ("We thus agree with the Government that the use of [patented technology] in preclinical studies is protected under §271(e)(1) *as long as there is a reasonable basis for believing that the experiments will produce 'the types of information that are relevant to an IND or NDA.'*" (emphasis added)). Thus, infringing activity may never occur.

Furthermore, given the broad scope of the § 271(e)(1) safe harbor, any non-safe harbor activities performed or products produced by Nucleonics would necessarily be in the area of animal therapy or research for animal therapy, with no application to human therapy. As Benitec explained before the Federal Circuit, it would have

no interest in suing Nucleonics in this area, in which it does not have commercialization rights and does not compete: the expense of a lawsuit to assert another party's rights does not make good business sense. Plaintiff-Appellee Benitec Australia, Ltd.'s Response to Defendant-Appellant Nucleonics' Supplemental Brief, filed March 5, 2007, at 6-8. *See also* J.A. 1528-52; J.A. 1530 at (B)(b); J.A. 1530-31(a-h); J.A. 1536-37 ¶ 4.3; *Benitec*, 495 F.3d at 1349, Pet. App. 21a ("Benitec has never challenged use of the technology in testing in animals for animal use and claims another company owns any right to do so.").

Additionally, Benitec would be precluded from suing Nucleonics over any activities or products in the animal arena without joining CSIRO, which owns the rights to the '099 Patent in the animal field. It has long been the law that, in order for patent infringement plaintiffs to have standing, the patent owner must be joined.[5] *See, e.g.*, *Independent Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459, 468 (1926). In the context of licensing, this Court has explained:

> [t]he patentee or his assigns may, by instrument in writing, assign, grant and convey, either, 1st, the whole patent, comprising the exclusive right to make,

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[5] Since the 1966 amendment of Federal Rule of Civil Procedure 19, "[a]s a general rule, [the Federal Circuit] continues to adhere to the principle set forth in *Independent Wireless* that a patentee should be joined, either voluntarily or involuntarily, in any infringement suit brought by an exclusive licensee." *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1377 (Fed. Cir. 2000).

> use and vend the invention throughout the United States; or, *2d, an undivided part or share of that exclusive right*; or, 3d, the exclusive right under the patent within and throughout a specified part of the United States.... A transfer of either of these three kinds of interests is an assignment, properly speaking, and vests in the assignee a title in so much of the patent itself, *with a right to sue infringers; in the second case, jointly with the assignor*; in the first and third cases, in the name of the assignee alone."

Waterman v. Mackenzie, 138 U.S. 252, 255 (1891) (citation omitted; emphasis added).

The division of rights to the '099 Patent corresponds to the second situation in *Waterman*: each of Benitec and CSIRO have an undivided part of the patent — the right to practice in humans or animals, respectively — each having their part of the patent right throughout the United States. *See also Pope Mfg. Co.*, 144 U.S. at 250 (addressing the question "whether a patentee can split up his patent into as many different parts as there are claims, and vest the legal title to those claims in as many different persons" and recognizing the rule that the patent monopoly "is for one entire thing, and that in order to enable the assignee to sue, the assignment must convey to him the entire and unqualified monopoly which the patentee held, in the territory specified, and that any assignment short of that is a mere license.").

The Federal Circuit has explicitly set forth the application of this rule to the co-owner relationship,

stating "[e]ven an ownership interest, however, would not be sufficient to give [putative patent co-owner] IBEP prudential standing to sue for infringement, as *IBEP would have to join all the other co-owners in order to establish such standing.*" *Israel Bio-Engineering Project v. Amgen Inc.*, 401 F.3d 1299, 1304-05 (Fed. Cir. 2005) (emphasis added)). "Absent the voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing." *Israel Bio-Engineering Project v. Amgen Inc.*, 475 F.3d 1256, 1264-65 (Fed. Cir.), *cert. denied*, 168 L. Ed. 2d 720 (2007).

Thus, CSIRO, an Australian research organization, would be a necessary party to resolution of any claim regarding animal rights. Because Benitec simply does not hold any of the bundle of rights to animal therapy or animal research for animal therapy, CSIRO is a necessary party even though a contract between CSIRO and Benitec, which was effective at the time that Benitec filed suit and at the time it filed its motion to dismiss, suggests that Benitec has the ability to file suit. *See, e.g., Propat Int'l Corp. v. RPost, Inc.*, 473 F.3d 1187, 1192 (Fed. Cir. 2007) (a right to sue clause did not confer the exclusive licensee with standing to sue since the plaintiff did not hold enough of the bundle of rights).

Nucleonics' vague wish to enter the animal field does not provide a basis for jurisdiction here.

3. Nucleonics' Alleged Agreement With A "Pharmaceutical" Company Does Not Support Jurisdiction.

After Benitec filed for dismissal, Nucleonics asserted that it had signed an agreement to work with a "pharmaceutical" company on an "exploratory collaboration" but that it did not perform due to vague "concerns about this litigation". Pet. for Reh'g at 4. *See also* J.A. 1410-11. Nucleonics asserts that its choice to stop this unspecified pre-dismissal work supports jurisdiction over its declaratory judgment claims because "*MedImmune* specifically holds that declaratory judgment jurisdiction is not defeated where a putative infringer — by virtue of coercion resulting from the patentee's threats — abstains from allegedly infringing activity that, if otherwise engaged in, would have supported jurisdiction" and complains that the Federal Circuit "departe[d] from *MedImmune*" in not considering "the fact that Nucleonics was coerced to end a collaboration, involving allegedly infringing activity...." Pet. 30-31. The Federal Circuit did not, however, need to decide whether *MedImmune* set such a low standard, as Nucleonics' asserted activity does not meet even this standard.

Nucleonics first raised this vague collaboration after Benitec moved to dismiss the litigation. Thus, Benitec never considered, much less alleged, that this collaboration was infringing. Indeed, despite pertinent discovery requests by Benitec, Nucleonics never provided Benitec enough information to even consider the question. Thus, referring to the collaboration as "allegedly infringing" is

disingenuous, especially in view of Nucleonics' statements that all of its research findings would become part of an IND submission to the FDA.

In its petition for rehearing by the Court of Appeals, Nucleonics asserted that this collaboration would "not [be] within the safe harbor [of § 271(e)(1)]". Pet. for Reh'g at 4. This unsworn attorney assertion is belied by (1)

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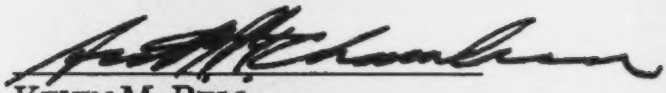
(*see* section III.A, *supra*); (2) the only information provided in Nucleonics' sworn declaration describing this work suggests that it *would* fall within the safe harbor (Pet. for Reh'g at 4 (describing the work as "exploratory collaboration" with a "pharmaceutical" company)); and (3) the breadth of the safe harbor, which makes it likely that any work in any way relevant to the use of the technology in humans would be exempt from infringement. Thus, on the factual record, the alleged corroboration does not support the exercise of jurisdiction.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Dated March 20, 2008

Respectfully submitted,



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IN THE

Supreme Court of the United States

NUCLEONICS, INC.,

Petitioner,

v.

BENITEC AUSTRALIA, LTD.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR PETITIONER

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INTRODUCTION AND SUMMARY OF REPLY

Petitioner Nucleonics, Inc. herein replies to Respondent Benitec Australia Ltd.'s Opposition to Nucleonics' Petition for a writ of certiorari.

Benitec attempts to characterize the present case as factually unique and complex and thus supposedly ill-suited as a vehicle for elucidation of Article III declaratory judgment jurisdiction. That is not the case. The issues presented by Petitioner are clear cut and transcend any supposed factual complexity that Benitec would mire them in. Indeed, taking Benitec's version of the facts as unassailable and fully supported by the record—which is not the case—does not in any way remove the fundamental Article III jurisdictional issue. Specifically:

> Can a party bring a patent infringement suit (telling the world that they have made a Rule 11 determination of infringement); withdraw that suit (for whatever reason) without prejudice; *retain* the *right* to *sue again* on the *same patent* and the *same allegedly infringing technology*; continue inflicting *present-day economic harm*; and nonetheless proclaim that the matter is "entirely terminated" and that the federal courts are stripped of jurisdiction to hear the invalidity counterclaim?

Whether *Cardinal Chemical*, *Altvater* and/or *MedImmune* permit jurisdiction under the present and analogous circumstances (as

Nucleonics urges) are real questions that need to be addressed—both to do justice in this case and to set out a rule of law that does not allow patentees to game the federal court system and inhibit innovation.

The dissent in the Federal Circuit recognized that jurisdiction should exist. Similarly, a line of cases from other Circuit Courts of Appeal—including *Leach v. Ross Heater & Mfg. Co.*, 104 F.2d 88 (2d Cir. 1939) (cited by this Court in *Altvater*) and numerous other cases cited in Nucleonics' Petition (at 20-21, 26) and below—have found counterclaim jurisdiction under virtually identical or analogous circumstances. Benitec's Opposition is absolutely silent about those cases.

Instead, Benitec proffers a myriad of irrelevant supposed detailed facts regarding: why they chose to withdraw their suit (be it a belief of temporary "safe harbor" status or a fear of invalidity); whether they have the power to sue over animal activity (something they had in fact sued over); whether their patent will have different (or even invalid) claims in the future after potentially years of re-examination in the Patent Office on issues different from those before the federal courts; and the exacting date (September 29, 2005) when Benitec's "covenant not to sue" ends and subsequent activities are at risk (Opp. at 12).

Petitioner respectfully submits that the real and transcendent legal issue here is whether a patentee can use federal litigation to bludgeon a competitor and then, in the face of adverse litigation events, temporarily withdraw,

retaining the threat of future action and the reality of present-day economic harm and coercion flowing therefrom (App. at 60a-62a) with no consequences for the patent. That issue should not be obscured here. A writ of certiorari should issue.

We reply in greater detail below to Benitec's legal and "factual" assertions.

Point I: *Cardinal Chemical* and *Altvater* Apply and Mandate Jurisdiction

Benitec proffers two basic arguments regarding *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993) and *Altvater v. Freeman*, 319 U.S. 359 (1943): (1) that Benitec's withdrawal without prejudice and without a covenant as to future activities *ipso facto* "entirely terminated" the controversy; and (2) that *Cardinal Chemical* and *Altvater* should not apply to district court jurisdiction where there has been no "judgment". (Opp. at 23-26).

First, Petitioner respectfully submits that the failure to covenant not to sue again on the same patent and the same technology—the only technology that Nucleonics practices—having already sued and made statements to the investing community about Nucleonics' infringement (Pet. at 5; App. at 52a), where present-day economic harm continues, cannot credibly be called "entire termination" of the controversy. *MedImmune* furthers this conclusion by recognizing that an imminent lawsuit is not required for declaratory jurisdiction. It is the threat of the patent—particularly where a suit has already been brought—and the economic

harm/coercion flowing therefrom that creates jurisdiction here. This controversy is not "entirely terminated."

Second, accepting that a judgment of non-infringement guarantees continuing jurisdiction over invalidity counterclaims (Opp. at i and 24-26), does not mean that the absence of a judgment precludes jurisdiction.

To the contrary, case law and logic urge—as did the Federal Circuit dissent (App. at 30a-32a)—that *Cardinal Chemical* and *Altvater* apply more broadly and allow for district court jurisdiction over counterclaims prior to judgment.

Benitec provides no satisfactory rationale for a constitutional distinction between a judgment of non-infringement and an "intervening event" (such as plaintiff withdrawing its infringement case)—arguing primarily that a judgment requires "great effort and expense". (Opp. at 25). However, if that is the test, then on-going economic harm after a protracted and costly district court litigation should also qualify for a finding of jurisdiction. The proposition that a patentee can avoid judgment by withdrawing (without prejudice) before judgment is an exercise in boot-strap circuitous logic. It allows the patentee to proclaim by fiat that jurisdiction has ended, without wholly resolving the controversy.

Numerous courts have recognized jurisdiction over invalidity counterclaims where a patentee attempts to withdraw their infringement case. (Pet. at 20-21, 24-26). In

Leach v. Ross Heater & Mfg. Co., 104 F.2d 88 (2d Cir. 1939), which was cited by *Altvater*, plaintiff's dismissal of the infringement action in the district court prior to any judgment did not moot invalidity counterclaims. *Hawley Prods. Co. v. United States Trunk Co.*, 259 F.2d 69 (1st Cir. 1958), cited *Altvater* and stated:

> Thus, although it might well be thought that to hold a patent invalid once it has been found not infringed would also be to decide a hypothetical case, the ***law since the Altvater case is settled*** that a court retains jurisdiction to hold a patent invalid ***even*** after it has been found not infringed. . . .
>
> when the [counterclaim] for a declaratory judgment was brought there certainly was an actual concrete dispute between the parties . . .
>
> ***And that dispute was not wholly laid at rest by the assertion . . . that by change of mind the charge of infringement had been dropped.***

Id. at 75-77 (emphasis added). *Hawley* parallels *Cardinal Chemical*'s "entirely terminated" language ("wholly laid at rest"); and cites *Altvater* as the ***extreme*** example for finding jurisdiction—where non-infringement had been adjudged ("*even*" then). *See also Lackner Co. v. Quehl Sign Co.*, 145 F.2d 932, 934 (6th Cir. 1944) ("In [*Altvater v. Freeman*] there was a decision of noninfringement, but nevertheless the Supreme

Court held that the counterclaim attacking validity was not disposed of by dismissal of the bill. Here, as pointed out, there has been no decision of noninfringement, and infringement is still asserted."); *Knaust Bros. v. Goldschlag*, 28 F. Supp. 188, 190-91 (S.D.N.Y. 1939)[1], *aff'd*, 119 F.2d 1022 (2d Cir. 1941). Thus, Benitec's "judgment" distinction is contrary to earlier cases that observed that a judgment of non-infringement, if anything, weakened the case for finding jurisdiction.

Benitec offers no comment on *Leach* or its progeny. Instead, they correctly state that the Federal Circuit has repeatedly refused to apply *Cardinal Chemical* and its analytic framework to issues of district court jurisdiction. (Opp. at 24). Of course, that only highlights the divide between the Federal Circuit's approach and that of the dissent in this case; that of other Circuit Courts; this Court's own citation to *Cardinal Chemical* in its *MedImmune* decision regarding

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[1] "I do not think that in the case of a patent, which is a claim of monopoly hanging over a trade, the plaintiff can suddenly, at the last moment, withdraw his claim of infringement and then claim, as the plaintiff's counsel now seeks to do, that the question of the validity has become moot. *Lewis Invisible Stitch Machine Co. v. Columbia Blindstitch Machine Mfg. Corp.*, D.C., 22 F. Supp. 705, 708, 709, and cf. *Basevi v. Edward O'Toole Co.*, D.C., 26 F. Supp. 41, 44 applying the same principle to copyrights. I think the plaintiff itself created a controversy by asserting the validity of the four claims of that patent and an infringement thereof. *Meiniecke v. Eagle Druggist Supply Co., Inc.*, D.C., 19 F. Supp. 523, 525. Inasmuch as a controversy was thus created by itself, the plaintiff cannot now, having once blown hot, be allowed to blow cold and claim that there was not any controversy."

district court jurisdiction (Pet. at 26); and what we believe is a proper reading of *Cardinal Chemical* itself.

At a minimum, whether *Cardinal Chemical* and *Altvater* apply, or should be extended to apply, to district court jurisdiction over invalidity counterclaims is ripe for decision by this Court—and is presented squarely by this case. Nothing in Article III, *Cardinal Chemical* or *Altvater* supports the proposition that patentee plaintiffs can bring suit, harass a defendant with their patent and then withdraw unscathed only to threaten suit again in the future, while inflicting present-day economic harm. Such a result would be anathema.

Respondent Benitec has not "entirely terminated" the present controversy. The invalidity counterclaims should be heard.

Point II: Benitec's and the Federal Circuit's "Immediacy [of Litigation]" Interpretation of *MedImmune*

Benitec argues that the "intervening event" of *Merck v. Integra*, 545 U.S. 193 (2005), made the *present litigation* not viable—a point never actually ruled upon by the District Court. (Opp. at 8-9, 27-28). Accepting this, *arguendo*, it does ***not*** follow that there is not a controversy of "sufficient immediacy and reality".

The flaw in Benitec's and the Federal Circuit's reasoning is simply that it equates a controversy singularly with an imminent litigation. That is the very proposition refuted in *MedImmune*, 127 S. Ct. 764 (2007). (Pet. at 28-30).

The "immediacy and reality" of the controversy here flows from the *present-day* economic harm being inflicted on Nucleonics. It flows from the *present-day* fact that Nucleonics must decide, *now*, whether to abandon *all* its activities or pursue them at risk—because *all* of its activities were broadly accused of infringement. Nucleonics must "bet the farm" as *MedImmune* so aptly put it.

In response, Benitec urges that we do not know what the future will bring and what future products Nucleonics will advance and hence what litigation will follow.[2] However, Benitec has asserted that an entire category of technology infringes, irrespective of temporary safe harbors. Consequently, Nucleonics faces the choice of pursuing that technology *now* or abandoning that technology *now*. Investors in Nucleonics face a similar choice.

There exists real economic harm and coercion *today* flowing from a legal controversy over the Benitec patent—even if an infringement lawsuit cannot be brought at this moment. Jurisdiction exists under *MedImmune*.

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[2] However, *Cardinal Chemical* noted that concerns about "similar products in the future" favor jurisdiction. *Cardinal Chemical*, 508 U.S. at 99-100 (quoted by the Federal Circuit dissent). *See also Hawley Products*, 259 F.2d at 76.

Point III: Brief Responses to Assorted Benitec Non-Sequitor "Facts"

A. The *Merck v. Integra* Safe Harbor Diversion

Benitec urges that the parties (a year before *Merck v. Integra*, 545 U.S. 193 (2005), and subsequent business and litigation developments) agreed that all of Nucleonics' human gene-silencing efforts and non-veterinary animal efforts are within the infringement safe harbor.

1. Transcendent Issues

Assuming Benitec is correct, the fundamental question of whether being in the safe harbor, in and of itself, should vitiate **counterclaim** jurisdiction remains. That question transcends the issue of whether the temporary safe harbor from litigation applies or not.

2. No Actual Judgment of "Safe Harbor" Non-Infringement

Furthermore, the District Court *never* issued a judgment that Nucleonics' activities were, as a matter of law, within the safe harbor.[3] This case ended because Benitec withdrew. "Safe harbor" status is ultimately a question of statutory law. 35 U.S.C. 271(e)(1); *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1028 (Fed. Cir. 1997). Questions of law cannot be stipulated by the parties. *Swift & Co. v. Hocking Valley Ry.*

[3] If there was a *judgment* of safe harbor non-infringement, Benitec should agree that *Cardinal Chemical* and *Altvater* apply.

Co., 243 U.S. 281, 289 (1917) ("If the stipulation is to be treated as an agreement concerning the legal effect of admitted facts, it is obviously inoperative; since the court cannot be controlled by agreement of counsel on a subsidiary question of law.").

3. The "Safe Harbor" Goes Only To The Merits

Even had there been a true judgment that Nucleonics' activities were within the temporary safe harbor, it would not bear on jurisdiction. *MedImmune* emphasizes the important distinction between disposing of a litigation on its "merits" and divesting a court of jurisdiction, stating:

> Of course even if respondents were correct that the licensing agreement or the common-law rule precludes this suit, the consequence would be that respondent would win this case *on the merits*—not that the very genuine contract dispute disappears, so that Article III jurisdiction is somehow defeated.

MedImmune, 127 S. Ct. at 776. This exacting observation is of direct relevance to the effect of *Merck v. Integra* on jurisdiction in the present case. While *Merck* may mean there is no present infringement, that goes only to the *merits* of Benitec's lawsuit with respect to infringement. It should not divest jurisdiction over invalidity counterclaims.

Merck v. Integra's "safe harbor" does not eliminate future liability from infringement, it simply postpones the time when liability begins. During the interim, when the putative infringer is shielded from patent liability, they are not shielded from other hardships that justify jurisdiction—such as the need to choose today to pursue or abandon the *already-accused* technology and the chill on investment resulting from fear of future patent liability for the same type of acts already sued upon.

Article III should not be seen to turn a blind eye to those present-day hardships. The very purpose of the infringement "safe harbor" was to promote innovation and research, not to hinder it by allowing invalid patents to wreak havoc unchallenged. It was not meant as a "safe harbor" for the patentee when they have already sued.

In sum, this issue is a "red-herring".

B. The Record Below As Regards *MedImmune* "Coerced Abstention"

The record below was formed well before *MedImmune* when no one comprehended the full relevance of abstained-from activities. Nonetheless, it contains *uncontradicted* sworn statements showing that Nucleonics lost a major contract with a major pharmaceutical company when it withdrew due to concerns about this litigation. (Pet. at 30-32; App. at 60a-61a).[4]

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[4] Benitec's suggestion (Opp. at 11) that it is impossible for any pharmaceutical research—even very preliminary basic biological inquiry—to be outside of the temporary safe harbor is, we would submit, inconsistent with this Court's holding in

If the record below is somehow unclear (Opp. at 11), a factual remand would have been appropriate given the change in the law created by *MedImmune*. *Cf. Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1369 (Fed. Cir. 2004). This option was noted to the Federal Circuit.

Beyond that, Nucleonics faces a "bet-the-farm" decision with respect to *all* of its accused endeavors going forward. *MedImmune* applies.

C. Benitec's "Animal Activity" Diversion

In the District Court, Benitec accused Nucleonics' animal activities of infringement in this litigation. (Pet. at 6). Safe harbor activity or not, Benitec clearly believed they had the right to assert the patent.

Benitec specifically refused to covenant not to sue on animal activity when questioned during the Federal Circuit argument. (Pet. at 16).

Benitec has *all litigation* rights—irrespective of "the right to practice". (Opp. at 33-34).

Benitec stated in an Annual Report that:

> Benitec's patent estate represents a dominant position . . . in RNAi

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Merck v. Integra. Benitec's accusation that Petitioner is "disingenuous" regarding the abstained-from activity being outside the safe harbor (Opp. at 35-36) is wrong. Petitioner's previous statements regarding actual activity and the safe harbor pertained to just that—actual ongoing activity. The abstained-from activity was stopped from going forward because of concerns that it was not in the safe harbor.

> application for ***humans and mammals***.

(App. at 51a).

Regardless, if needed, Benitec's co-owner CSIRO can be joined as a co-plaintiff.

This "issue" formed no basis for the decisions below.

It is a non-issue.

D. Benitec's "Re-Examination" Diversion

Benitec's patent has been in Patent Office re-examination since 2004. However, re-examination never divests Article III jurisdiction.

Courts routinely hear patent litigations despite simultaneous re-examinations (which can take many years to conclude)—particularly where the issues before the court are different from those before the Patent Office.[5] The inequitable conduct inventorship issue here is solely before the District Court.

This "issue" formed no basis for the decisions below.

Again, this is a non-issue.

Point IV: This Case Is Well-Situated for Review

Contrary to Benitec's disparate assertions, this case is neither singularly limited to its

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[5] *VisKase Corp. v. American Nat'l Can*, 261 F.3d 1316, 1327-28 (Fed. Cir. 2001).

particular facts[6] (Opp. at 1, 15) nor does it call for a sweeping holding (Opp. at 19-20) that all patentees be subject to declaratory judgment actions per se.

At a minimum, a plaintiff who sues and will not fully walk away from future litigation against a defendant whose entire business is devoted to the accused technology, thereby inflicting economic harm, should be seen to subject his patent to scrutiny. A contrary rule would allow invalid patents to be wielded with impunity to the detriment of innovation and economy.

The Court can judiciously resolve this case, while clarifying apparent rifts in the case law and more clearly defining the scope of Article III jurisdiction.

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[6] Since our last writing in late December 2007 (Pet. at 19 n.8), the number of lower court cases citing the Federal Circuit's decision in *Benitec v. Nucleonics*, 495 F.3d 1340 (Fed. Cir. 2007), has increased from eleven to twenty.

CONCLUSION

For the reasons stated here and previously, the petition for a writ of certiorari should be granted.

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Respectfully submitted,

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